DRAFT

Background Document

Rulemaking Issues Related To Application Of The Toxicity Equivalency Factor (TEF) Methodology For Mixtures Of Polychlorinated dibenzo-p-dioxins / Polychlorinated dibenzofurans (Dioxins/Furans), Polycyclic aromatic hydrocarbons (PAHs) and Polychlorinated biphenyls (PCBs)

July 2006

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List of Abbreviations and Acronyms

General

ARARs	Applicable or Relevant and Appropriate Requirements
ASTSWMO	Association of State & Territorial Solid Waste Management Officials
B(a)P	Benzo[a]pyrene
Cal EPA	California Environmental Protection Agency
CLARC	Cleanup Levels and Risk Calculation Guidance Document
CDDs	Polychlorinated dibenzo-p-dioxins
CDFs	Polychlorinated dibenzofurans
Ecology	Washington Department of Ecology
EPA	U. S. Environmental Protection Agency
HpCB	Heptachlorobiphenol
HpCDD	Heptachlorodibenzo-p-dioxin
HpCDF	Heptachlorodibenzofuran
HxCB	Hexachlorobiphenyl
HxCDD	Hexachlorodibenzo-p-dioxin
HxCDF	Hexachlordibenzofuran
IRIS	Integrated Risk Information System
MTCA	Model Toxics Control Act
PAHs	Polycyclic aromatic hydrocarbons
PCBs	Polychlorinated biphenyls
PeCB	Pentachlorobiphenyl
PeCDD	Pentachlorodibenzo-p-dioxin
PeCDF	Pentachlorodibenzofuran
PEF	Potency Equivalency Factor
OCDD	Octachlorodibenzo-p-dioxin
ODCF	Octoachlorodibenzofuran
RPF	Relative Potency Factor
TCDD	2, 3, 7, 8-Tetrachlorodibenzo-p-dioxin
TeCB	Tetrachlorobiphenyl
TCP	Toxics Cleanup Program
TEC	Toxicity Equivalent Concentration
TEF	Toxicity Equivalency Factor
TEQ	Total toxicity equivalent concentration or total toxicity equivalence
WAC	Washington Administrative Code
WHO	World Health Organization
10^{-6}; $1 X 10^{-6}$	One in one million risk level
10^{-5}; $1 X 10^{-5}$	One in one hundred thousand risk level

Weight and Concentration Units

kg	Kilogram
g	Gram, one thousandth of a kilogram, 1 X 10^{-3} kg
mg	Milligram, one-millionth of a kilogram, 1 X 10^{-6} kg
µg	Microgram, one-billionth of a kilogram, 1 X 10^{-9} kg
ng	Nanogram, one-trillionth of a kilogram, 1 X 10^{-12} kg
pg	Picogram, one-quadrillionth of a kilogram, 1 X 10^{-15} kg

ppm	Parts per million (mg/kg; mg/L)
ppb	Parts per billion (µg/kg; µg/L)
ppt	Parts per trillion (ng/kg; ng/L)
ppq	Parts per quadrillion (pg/kg; pg/L)

1 Introduction

1.1 Overview

The Department of Ecology (Ecology) has begun a rulemaking process to amend the Model Toxics Control Act (MTCA) Cleanup Regulation (Chapter 173-340 WAC). This rulemaking will clarify the policies and procedures for establishing cleanup levels for mixtures of polychlorinated dibenzo-p-dioxins/ polychlorinated dibenzofurans, polycyclic aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs).

Ecology has prepared this document in order to assist public review and discussion of the MTCA rule revisions being considered by the Toxics Cleanup Program (TCP). Specifically, the document is designed to achieve two main purposes:

- Describe the revisions that Ecology plans to make to the MTCA Cleanup Regulation.
- Describe the key rulemaking issues that Ecology considered when preparing the draft rule revisions, options for resolving those issues and Ecology's rationale for choosing particular options when preparing the draft rule revisions.

1.2 Reasons for the Rulemaking

Ecology amended the MTCA rule in February 2001, with an effective date of August 15, 2001. Under the rule amendments, a person undertaking a cleanup action may use the Environmental Protection Agency's toxicity equivalency factor (TEF) values and methodology when assessing dioxin and furan mixtures. However, the MTCA rule does not clearly specify how the TEF values should be used within the framework for establishing Method B cleanup levels.

In late 2001, Ecology published procedures that explain how to apply the TEF methodology when establishing cleanup levels. These procedures are part of a larger guidance document – the Cleanup Levels and Risk Calculation (CLARC) guidance document (Ecology, 2006).

In November 2005, the Rayonier Corporation filed a lawsuit challenging Ecology's application of CLARC guidance document at the Port Angeles mill site. The lawsuit exposed an ambiguity in the MTCA rule with respect to the policies and procedures for establishing cleanup levels for mixtures of dioxins and furans. In April 2006, Ecology settled the lawsuit and agreed that Rayonier's approach was an acceptable interpretation of the current MTCA rule.

In March 2006, several environmental organizations requested that Ecology issue an emergency rule amendment to clarify the policies and procedures for establishing cleanup levels for dioxins/furans, PAHs, and PCBs. Ecology reviewed the request and decided to initiate a focused rule revision process. Ecology decided that amending the MTCA rule to clarify key policy decisions is preferable to repeatedly resolving this issue on a site-specific basis.

1.3 Rulemaking Schedule

Ecology has established an ambitious schedule for amending the rule by the end of 2006. Ecology initiated the rulemaking process on June 7, 2006 by filing the CR-101 with the Office of the Code Reviser. During the June through August time period, Ecology plans to:

- Prepare draft rule language;

- Complete evaluations needed to comply with the State Environmental Policy Act, the Regulatory Fairness Act and the Administrative Procedures Act; and
- Meet with interested groups and individuals to discuss rulemaking issues.

Ecology plans to publish the proposed rule for formal public comment in late August or early September 2006. Public hearings will be held in late September 2006. Ecology will then review the public comments and make a final decision on the rule amendments by the end of 2006.

1.4 Relationship to 5-Year Rule Review

Ecology's actions to clarify the methods and procedures for evaluating mixtures of dioxins/furans, PAHs, and PCBs is the first phase of a two-phase process. In the second phase of the process, Ecology will conduct the five-year review process specified in the MTCA rule. WAC 173-340-702 (11) states that the Department of Ecology will review and, as appropriate, update WAC 173-340-700 through 173-340-760 at least once every five years.

Ecology plans to initiate the five-year rule review process in late 2006 following the completion of this focused rulemaking. As part of the review process, Ecology plans to hold several scoping meetings to obtain recommendations on issues and/or rule provisions. Ecology will review the public comments and then decide (1) whether to begin a second rulemaking phase and (2) what issues will be addressed during the second rulemaking phase.

1.5 Organization of the Document

The remaining parts of this document are organized into the following sections:

- **Section 2 – Background Information:** This section provides a brief summary of the MTCA Cleanup Regulation and the TEF methodology and describes how the TEF methodology has been used to establish cleanup levels.
- **Section 3 - Description of the Draft Rule Revisions**: This section summarizes the rule revisions that Ecology is considering during the rulemaking process.
- **Section 4 – Rulemaking Issues:** This section provides a discussion of nine key policy and technical issues central to this rulemaking effort. The section is divided into nine subsections (one issue per subsection) that include:
    - A brief description of the issue;
    - The options for resolving the issue; and
    - Ecology's preferred option and the rationale for choosing that option.
- **Section 5 – References**
- **Section 6 – Representative Structural Formulas**

2 Background Information

2.1 MTCA Cleanup Standards

The Model Toxics Control Act (MTCA), chapter 70.105D RCW, was passed by the voters of the State of Washington in November 1988 and became effective March 1, 1989. The law establishes the basic authorities and requirements for cleaning up contaminated sites throughout Washington State. The objective of (MTCA) is to prevent or remedy threats to human health and the environment posed by hazardous waste sites.

RCW 70.105D 030(2)(e) directs Ecology to "...[p]ublish and periodically update minimum cleanup standards for remedial actions at least as stringent as the cleanup standards under section 121of the federal cleanup law, 42 U.S.C. Sec. 9621, and at least as stringent as all applicable state and federal laws, including health-based standards under state and federal law..."

Ecology originally adopted the cleanup standards in February 1991. Ecology initiated a negotiated rulemaking process in 1997 that resulted in significant amendments to the cleanup standards provisions that were adopted in February 2001 and became effective on August 15, 2001.

The MTCA rules establish three methods (Methods A, B and C) for establishing cleanup levels. The following discussion provides a brief summary of the Methods and is not intended to capture all aspects of establishing cleanup levels under these methods. See WAC 173-340 for the specific requirements for these methods:

- ***Method A*** is typically used to establish cleanup levels at relatively small sites that involve few contaminants. Under Method A, cleanup levels for carcinogens must be at least as stringent as the following:
    - Method A Tables: Method A cleanup levels established in Tables 720-1, 740-1, and 745-1.
    - Applicable & Relevant & Appropriate Requirements (ARARs): Standards in applicable state and federal laws (such as the surface water quality criterion, standards, in the National Toxics Rule).
- ***Method B*** is the universal method for establishing cleanup levels and can be used at any site. Under Method B, cleanup levels for carcinogens must be at least as stringent as the following:
    - Applicable & Relevant & Appropriate Requirement (ARARs): Standards in applicable state and federal laws.
    - Individual Hazardous Substances: The cancer risk for individual substances cannot exceed one in one million (1×10^{-6}). The non-cancer risk for individual substances cannot exceed a hazard quotient of one (1).
    - Total Site Risk: The total site risk for carcinogens cannot exceed one-in-one hundred thousand (1×10^{-5}). Non-cancer total site risk cannot exceed a hazard index one (1). The MTCA rules require that the cleanup levels established for individual substances be adjusted downward if the total risk posed by the entire mixture exceeds either of these

limits. Total site risk includes consideration of multiple hazardous substances and multiple pathways of exposure.

- ***Method C*** is a conditional method that is only allowed to be used in certain limited situations. It is typically used to establish soil cleanup levels for industrial land uses. Under Method C, cleanup levels for carcinogens must be at least as stringent as the following:

  - Applicable & Relevant & Appropriate Requirements (ARARs): Standards in applicable state and federal laws.

  - Individual Hazardous Substances: The cancer risk for individual substances cannot exceed one in one hundred thousand (1×10^{-5}). The non-cancer risk for individual substances cannot exceed a hazard quotient of one (1).

  - Total Site Risk: The total site risk for carcinogens cannot exceed one-in-one hundred thousand (1×10^{-5}). Non-cancer total site risk cannot exceed a hazard index of one (1). The MTCA rules require that the cleanup levels established for individual substances be adjusted downward if the total risk posed by the entire mixture exceeds either of these limits. Total site risk includes consideration of multiple hazardous substances and multiple pathways of exposure.

2.2 Toxicity Equivalency Factors

Complex environmental mixtures are composed of multiple chemical components. The toxicity equivalency methodology is a tool to evaluate the toxicity and assess the risks of complex environmental mixtures that have similar structure-activity relationships and have a common mode of action.

The toxicity equivalency methodology is usually applied to the complex environmental mixtures of dioxins and furans, PAHs, and dioxin-like PCBs. The adverse biological effects from exposures to these mixtures are assumed to be additive (EPA, 2000; Cal EPA, 2005). The toxicity of complex environmental mixtures is predicted by scaling the toxicity of the components of the mixture, relative to an index chemical (EPA, 2000).

Toxicity equivalency factors (TEFs) provide an order of magnitude estimate of potency relative to an index chemical. In the case of dioxin-like chemicals, they are based on scientific judgment and consensus of international groups of scientists (Birnbaum and DeVito, 1995; Van den Berg et. al., 1998; Hawes et al. 2006; Van den Berg et al., 2006) and are supported by recent empirical data (Walker et al., 2005). A committee formed by the National Academy of Sciences to review EPA's dioxin reassessment report concluded that the "...the toxic equivalency factor methodology provides a reasonable, scientifically justifiable, and widely accepted method to assess the relative potency of DLCs..." (NAS, 2006, p. 6)[1].

In February 2001, Ecology revised WAC 173-340-708(8) by adding new provisions applicable to mixtures of chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans and polycyclic aromatic hydrocarbons:

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[1] The NAS committee also recommended that EPA acknowledge the need for better uncertainty analysis of the toxicity values and should include an initial uncertainty analysis of overall toxicity in the final EPA report.

- Dioxins/Furans: WAC 173-340-708(8)(d) states that cleanup proponents may use EPA's TEF values and methodology when assessing the potential carcinogenic risk of mixtures of chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans[2]. Under the EPA methodology, 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) is the index chemical. The total toxicity equivalent concentration of the mixture is represented by the sum of the products of the TEF and the concentration of the respective dioxin or furan congener (see Section 2.3);

- Polycyclic Aromatic Hydrocarbons (PAHs): WAC 173-340-708(8)(d) states that cleanup proponents may use the Relative Potency Factors (RPFs) and methodology developed by the California Environmental Protection Agency (Cal-EPA) when assessing the potential carcinogenic risk of mixtures of polycyclic aromatic hydrocarbons[3]. Under the Cal-EPA methodology, benzo[a]pyrene [B(a)P] is the index chemical. The total toxicity equivalent concentration of the mixture is represented by the sum of the products of the TEF and the concentration of the respective PAH compounds.

2.3 Cleanup Levels and Risk Calculation (CLARC) Guidance Published in 2001

In November 2001, Ecology published procedures that describe how to use the TEF methodology when establishing cleanup levels for dioxins/furans and PAHs. These procedures are part of a larger guidance document – the Cleanup Levels and Risk Calculation (CLARC) guidance document (Ecology, 2006). The CLARC guidance document mirrors the MTCA rule in that it describes two procedures for identifies two methods for establishing cleanup levels for either of these two types of mixtures:

- Method Number 1: Default approach. With this method, the entire mixture is assumed to be as toxic (equipotent) as the index chemical for the mixture. The toxicity of mixtures of dioxins and furans and the are assumed to be equipotent to the index chemical, TCDD. The toxicity of mixtures of PAHs are assumed to be equipotent to the index chemical B(a)P. The medium-specific Method B/C cleanup levels for TCDD and B(a)P are used as the cleanup levels for their respective mixtures.

- Method Number 2: The toxicity equivalency factor (TEF) methodology. The toxicity equivalency methodology is applied to the complex environmental mixtures of dioxins and furans, and PAHs. The total equivalency (TEQ) or total toxicity equivalent concentration (TTEC) of a mixture is the sum of the products of the concentration of each congener in the contaminated medium and its TEF (See Figure 1).

[2] WAC 173-340-708(8) does not require people to use the TEF methodology when assessing dioxin/furan mixtures. A cleanup proponent may choose to assess the carcinogenic risks of dioxin/furan mixtures by assuming that the entire mixture is as toxic as 2,3,7,8 TCDD.
[3] WAC 173-340-708(8) does not require people to use the TEF methodology when assessing PAH mixtures. A cleanup proponent may choose to assess the carcinogenic risks of PAH mixtures by assuming that the entire mixture is as toxic as benzo[a]pyrene.

Figure 1: Characterizing Dioxin and Furan Mixtures

$$\text{Total Toxicity Equivalence (TEQ)} = \sum C_n * TEF_n$$

Where:

TEQ = Total Toxicity Equivalence

TEF_n = Toxic equivalency factor of the individual congener associated with its respective mixture

C_n = Concentration of the individual congener in the mixture

The toxicity equivalency for mixtures of dioxins and furans, PAHs, and dioxin-like PCBs are determined as follows:

- Analyze a sample from the medium of concern to determine the congeners and the concentration of each congener;
- Multiply each congener concentration identified in the sample by the applicable toxicity equivalency factor to obtain a toxicity equivalent concentration; and
- Add the products of the concentration of each congener and its TEF to obtain the total equivalency of the mixture (TEQ) or total toxicity equivalent concentration.

To determine compliance, the total toxicity equivalent concentration for the sample is then compared to the applicable cleanup level (or remediation level, if applicable) for the index chemical. NOTE: If statistics are being used to determine compliance, then the upper bound estimate of the mean of multiple samples would be compared to the cleanup level (or remediation level). If the total toxicity equivalent concentration for the sample (or upper bound of multiple samples) exceeds the Method B/C cleanup level (or remediation level) for the index chemical, then the cleanup level has not been met.

2.4 Legal Challenge to Use of the CLARC Guidance

In November 2005, the Rayonier Corporation filed a lawsuit challenging Ecology's interpretation of the MTCA rule provisions related to the use of the TEF methodology. Rayonier argued that (1) each congener should be considered an individual hazardous substance and (2) cleanup levels for each congener should be established at concentrations corresponding to an incremental cancer risk of one-in-one million (10^{-6}). In April 2006, Ecology settled the lawsuit and agreed that Rayonier's approach was an acceptable interpretation of the current MTCA rule.

3 Description of the Proposed Draft Rule Revisions

Ecology has identified several rule revisions that are intended to clarify the policies and procedures for calculating excess cancer risk and determining compliance with cleanup levels and remediation levels for mixtures of polychlorinated dibenzo-p-dioxins/ polychlorinated dibenzofurans, polychlorinated biphenyls (PCBs), and polycyclic aromatic hydrocarbons (PAHs). The draft rule revisions include:

Polychlorinated dibenzo-p-dioxins/ Polychlorinated dibenzofurans

- WAC 173-340-708(8) includes new language that is intended to clarify that mixtures of dioxins and furans will be considered a single hazardous substance for calculating excess cancer risk and determining compliance with cleanup levels and remediation levels. This means a 1 x 10^{-6} cancer risk is applied to the mixture under Method B and a 1 x 10^{-5} cancer risk is applied to the mixture under Method C.
- The draft rule has been updated to incorporate the most recent toxicity equivalency factors (TEFs) for dioxins/furans recommended by the World Health Organization. The updated TEF values are included in a new table (708-1).
- The proposed rule revisions describe the policies and procedures for using the Toxicity Equivalency Factor (TEF) methodology and the total toxicity equivalent concentration representative of mixtures of polychlorinated dibenzo-p-dioxins/ polychlorinated dibenzofurans to calculate excess cancer risks and determine compliance with cleanup and remediation levels.

Carcinogenic Polycyclic aromatic hydrocarbons (carcinogenic PAHs)

- WAC 173-340-708(8) includes new language that is intended to clarify that mixtures of carcinogenic PAHs will be considered a single hazardous substance for calculating excess cancer risk and determining compliance with cleanup levels and remediation levels. This means a 1 x 10^{-6} cancer risk is applied to the mixture under Method B and a 1 x 10^{-5} cancer risk is applied to the mixture under Method C.
- The draft rule has been updated to incorporate the most recent toxicity equivalency factors (TEFs) for carcinogenic PAHs developed by the California Environmental Protection Agency. The updated TEF values are included in a new table (708-2).
- The proposed rule revisions describe the policies and procedures for using the Toxicity Equivalency Factor (TEF) methodology and the total toxicity equivalent concentration representative of mixtures of carcinogenic PAHs to calculate excess cancer risks and determine compliance with cleanup and remediation levels.
- WAC 173-340-708(8) continues to specify that, at a minimum, the~~se~~ seven most common carcinogenic PAH compounds must be included in the analysis when using the TEF approach to characterize carcinogenic PAH mixtures.

Polychlorinated biphenyls (PCBs)

- WAC 173-340-708(8) includes new language that is intended to clarify that PCB mixtures will be considered a single hazardous substance for calculating excess cancer risk and determining compliance with cleanup levels and remediation levels. This means a 1 x 10^{-6} cancer risk is applied to the mixture under Method B and a 1 x 10^{-5} cancer risk is applied to the mixture under Method C.

- The draft rule incorporates the most recent toxicity equivalency factors for dioxin-like PCB congeners recommended by the World Health Organization. The TEF values for dioxin-like PCBs are included in Table 708-1.

- The proposed rule revisions describe the policies and procedures for using the Toxicity Equivalency Factor (TEF) methodology and the total toxicity equivalent concentration representative of mixtures of polychlorinated biphenyls (PCBs) to calculate excess cancer risks and determine compliance with cleanup and remediation levels.

General Provisions

- WAC 173-340-708(8) requirement that, when using TEFs, carcinogenic PAH-specific properties and dioxin/furan/PCB congener-specific properties be used when using modeling to predict cross-media impacts.
- The terminology for dioxins in Tables 749-2, 749-3 & 749-5 is changed to make it internally consistent with Section 708.

4 Rulemaking Issues

Ecology staff and management considered a wide range of issues when preparing the draft rule revisions. Table 4.1 identifies nine issues that are central to this rulemaking. This section is divided into nine subsections (one issue per subsection) that include (1) a brief description of the issue; (2) the options for resolving the issue; and (3) Ecology's proposed option and the rationale for choosing that option.

Figure 2
Key Rulemaking Issues

Dioxin/Furan Mixtures

Issue #1	When characterizing the carcinogenic risks of dioxin/furan mixtures, should Ecology use the EPA-89 TEF values or the WHO-98 TEF values?
Issue #2	Should dioxin/furan mixtures be treated as a single hazardous substance or a mixture of multiple hazardous substances when calculating excess cancer risks and determining compliance with cleanup and remediation levels under MTCA?

PAH Mixtures

Issue #3	When characterizing the carcinogenic risks of PAH mixtures, should Ecology use the RPF/TEF values in the 2005 California EPA Guidance Document?
Issue #4	When characterizing the carcinogenic risks of PAH mixtures, should Ecology continue to focus its' evaluation on the seven PAH compounds identified in the current MTCA rule?
Issue #5	Should PAH mixtures be treated as a single hazardous substance or a mixture of multiple hazardous substances when calculating excess cancer risks and determining compliance with cleanup and remediation levels under MTCA?

PCB Mixtures

Issue #6	Should Ecology amend the MTCA rule to explicitly allow or require the use of the WHO-1998 TEF values and methodology to assess the carcinogenic risks of PCB mixtures?
Issue #7	Should PCB mixtures be treated as a single hazardous substance or a mixture of multiple hazardous substances when calculating excess cancer risks and determining compliance with cleanup and remediation levels under MTCA?
Issue #8	How should Ecology take into account non-dioxin-like health effects when using the TEF methodology to assess PCB mixtures?

General Issues

Issue #9	How should Ecology apply the TEF methodology when evaluating cross-media impacts?

Choice of TEF Values for Dioxin/Furan Mixtures

Issue #1

When characterizing the carcinogenic risks of dioxin/furan mixtures, should Ecology use the EPA-89 TEF values or the WHO-98 TEF values?

Background

Dioxins and furans are generally present in the environment as a complex mixture of chemical "congeners" that differ in terms of the number and location of chlorine atoms. 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) is the most toxic and best-studied of the 210 polychlorinated dibenzo-p-dioxin and polychlorinated dibenzofuran congeners (CDDs and CDFs). Because of the need to evaluate the risks associated with the whole mixture, scientists have developed the "Toxicity Equivalency Factor" or "TEF" methodology. Under this approach, each congener is assigned a TEF, which is some fraction of the toxicity of TCDD. The total toxic equivalency (TEQ) of a mixture is the sum of the products of the concentration of each congener in the contaminated medium and its TEF.

The TEF methodology has evolved over the last twenty years as a result of scientific reviews and evaluations conducted by several organizations. EPA first adopted the TEF concept as an interim procedure for evaluating the toxicity and risks associated with exposures to dioxin and furan mixtures (EPA, 1987). EPA subsequently updated its TEF values based on international consensus regarding the interpretation of relevant toxicological information for dioxin and furan mixtures. (EPA, 1989)[4].

The World Health Organization (WHO) and International Programme on Chemical Safety (IPCS) initiated a joint project in 1997 to review available toxicity data for dioxin-like compounds. The expert panel completed its evaluation and published recommended TEF values (Van den Berg, et al., 1998). These values are generally referred to as the WHO-98 TEFs. Table 1 compares the WHO-98 TEF values with the earlier EPA values.

The majority of state, federal and international environmental agencies currently use the WHO-98 values when evaluating the health risks posed by dioxin/furan mixtures. For example, EPA uses the WHO-1998 TEF values when evaluating health risks (EPA, 2001; US EPA, 2003c).

There are two ongoing and/or recently completed reviews addressing the TEF methodology and TEF values. The World Health Organization convened a meeting of scientific experts in June 2005 to review the WHO-98 TEF values and other related issues. The scientific experts participating in that meeting recommended changes to the TEF for four of the seventeen dioxin and furan congeners (See Table 1). The results of that meeting are summarized in Van den Berg et al. (2006). In 2004, EPA asked the National Academy of Sciences to review the agency's Dioxin Reassessment Report. The NAS report was recently published and the commitee concluded that the "...the toxic equivalency factor methodology provides a reasonable,

[4] The MTCA Cleanup Regulation (WAC 173-340-708(8)) references the 1989 EPA document and specifies that those TEFs may be used when assessing the potential carcinogenic risk of dioxin/furan mixtures.

scientifically justifiable, and widely accepted method to assess the relative potency of DLCs..." (NAS, 2006, p. 6)[5].

Table 1					
Toxicity Equivalency Factors (TEFs) For CDDs/CDFs					
Congener	**EPA/87[6]**	**EPA/89[3] (Current MTCA Rule)**	**NATO/89[7]**	**WHO 98[8]**	**WHO2005 TEFs[9]**
TEFs for CDDs					
2,3,7,8-TCDD	1	1	1	1	1
1, 2,3,7,8-PeCDD	0.5	0.5	0.5	1	1
1, 2,3,4,7,8-HxCDD	0.04	0.1	0.1	0.1	0.1
1,2,3,6,7,8-HxCDD	0.04	0.1	0.1	0.1	0.1
1,2,3,7,8,9-HxCDD	0.04	0.1	0.1	0.1	0.1
1,2,3,4,6,7,8-HpCDD	0.001	0.01	0.1	0.01	0.01
1,2,3,4,6,7,8,9-OCDD	0	0.001	0.001	0.0001	0.0003
TEFs for CDFs					
2,3,7,8-TCDF	0.1	0.1	0.1	0.1	0.1
1,2,3,7,8-PeCDF	0.1	0.05	0.05	0.05	0.03
2,3,4,7,8-PeCDF	0.1	0.5	0.5	0.5	0.3
1,2,3,4,7,8-HxCDF	0.01	0.1	0.1	0.1	0.1
1,2,3,6,7,8-HxCDF	0.01	0.1	0.1	0.1	0.1
1,2,3,7,8,9-HxCDF	0.01	0.1	0.1	0.1	0.1
2,3,4,6,7,8- HxCDF	0.01	0.1	0.1	0.1	0.1
1,2,3,4,6,7,8-HpCDF	0.001	0.01	0.01	0.01	0.01
1,2,3,4,7,8,9- HpCDF	0.001	0.01	0.01	0.01	0.01
1,2,3,4,6,7,8,9-OCDF	0	0.001	0.001	0.0001	0.0003

MTCA Rulemaking Options

Ecology has considered three options for this rulemaking issue:

1. EPA-89 Values: Under this option, Ecology would continue to use the TEF values from the 1989 EPA Guidance Document when assessing mixtures of dioxins and furans;

2. WHO-1998 Values: Under this option, Ecology would revise the MTCA rule to specify that the WHO-98 TEF values should be used when evaluating mixtures of dioxins and furans.

3. WHO-2005 Values: Under this option, Ecology would revise the MTCA to specify that the most current WHO TEF values should be used when evaluating mixtures of dioxins and furans. [The WHO convened a meeting of scientific experts in June 2005 to re-evaluate the 1998 TEF values. The results of the June 2005 meeting are presented in Van den Berg et al. (2006)[10]. This information was published after Ecology distributed draft rule language for public review.]

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[5] The NAS committee also recommended that EPA acknowledge the need for better uncertainty analysis of the toxicity values and should include an initial uncertainty analysis of overall toxicity in the final EPA report.
[6] U.S. EPA's 1989. Update to the Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-dioxins and-dibenzofurans (CDDs and CDFs), EPA/625/3-89/016, March 1989.
[7] NATO/CCMS. (1988) Scientific basis for the development of the International Toxicity Equivalency Factor (I-TEF) method of risk assessment for complex mixtures of dioxins and related compounds. Report No. 178, Dec. 1988.
[8] Van den Berg, M; Birnbaum, L; Bosveld, ATC; et al. (1998) Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environ Health Perspect 106(12):775-792.
[9] Van den Berg et al. (2006).
[10] The scientific experts expressed continued support for the TEF approach. However, they identified changes to the TEF values for four of the seventeen dioxin and furan congeners: 2,3,4,7,8-pentachlorodibenzofuran (TEF

Ecology's Rulemaking Proposal and Rationale

In the draft rule revisions distributed in June 2006, Ecology proposed to revise WAC 173-340-708(8) to specify that the WHO-98 TEF values should be used when assessing the carcinogenic risk of mixtures of dioxins and furans (Option 2). Ecology is also considering specifying the use of the WHO-2005 values that were published on-line in early July. Ecology's rationale for using more current TEF values includes the following:

- Biological Basis for the TEF Methodology. The TEF methodology is a relative potency approach that is grounded in the concept that dioxin/furan mixtures act through a common mechanism of action that involves binding the Ah receptor (aryl hydrocarbon hydroxylase receptor, enzyme induction) and, consequently, behave as a single chemical. The concept of potency-adjusted additivity has been evaluated for a number of toxic endpoints. Of particular relevance to the current discussion, Walker et al. (2005) evaluated the dose-additive carcinogenicity of a mixture of dioxin-like compounds and found that (1) the dose-response for the mixture could be predicted from a combination of the potency-adjusted doses of the individual congeners; (2) the WHO-98 TEF values adequately predicted the increased incidence of liver tumors associated with exposure to a mixture of dioxin-like compounds; and (3) the shapes of the dose-response curves were the same in the studies of three individual congeners and the mixture.

- Scientific Basis for the WHO-98 TEF Values: The WHO-98 TEF values reflect a scientific consensus on the relative toxicity of dioxin-like compounds. These values were developed after a rigorous scientific review performed by international experts. More recent scientific reviews by the EPA Risk Assessment Forum (EPA, 2000), EPA's Science Advisory Board (EPA, 2001) and the National Research Council (NAS, 2003; NAS, 2006) have re-affirmed the scientific basis for these values. The NAS panel (2006) recommended that EPA consider the results of the WHO/IPCS review when revising the dioxin reassessment report.

- Scientific Uncertainty: Ecology recognizes that there are uncertainties in the TEF values and the application of this approach to predict health risks and calculate cleanup levels. However, a scientific panel convened by EPA and the Department of Interior concluded that "...the uncertainties associated with using RePs or TEFs are not thought to be larger than other sources of uncertainty within the risk assessment process (e.g. dose-response assessment, exposure assessment and risk characterization)..."(EPA, 2001b). The EPA Science Advisory Board also noted that five of the 30 dioxin-like compounds (17 PCDDs/PCDFs and 13 PCBs) considered by EPA account for over 70% of the TEQ in the human diet. The Board noted that the variability in relative potency factors for these five congeners is much lower than the variability in TEFs for congeners that are minor contributors to human exposure (EPA, 2001a). Hawes et al. (2006) reached similar conclusions.

- Approaches Used by TCP and Other Environmental Agencies: The use of the more current TEF values is consistent with the current MTCA rule and reflects a logical update based on more recent scientific information. Numerous agencies currently use the WHO-98 TEF values when evaluating the health risks associated with dioxin and furan mixtures. For example:
  - The Water Quality Program used the WHO-98 TEFs when establishing the Total Maximum Daily Load (TMDL) for Lake Chelan (Ecology, 2005).
  - The Environmental Assessment Program used the WHO-98 TEFs to prepare the 2004 303(d) list of impaired water bodies (Ecology, 2004).

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revised from 0.5 to 0.3); 1,2,3,7,8-pentachlorodibenzofuran (TEF revised from 0.05 to 0.03); and octachlorodibenzo-p-dioxin and octachlorodibenzofuran (TEF revised from 0.0001 to 0.00003)

  - The Solid Waste and Financial Assistance Program used the WHO-98 TEFs when preparing the initial list of persistent, bioaccumulative toxins (PBTs).
  - EPA used the WHO-98 TEF values when preparing the 2003 dioxin reassessment report.
  - The EPA Superfund program recommends that the WHO-98 TEF values be used when evaluating the health risks posed by dioxin/furan mixtures.
  - EPA used the WHO-98 TEF values when establishing reporting requirements for dioxin and dioxin-like compounds under Section 313 of the Emergency Planning and Community Right-to-Know Act.
  - ATSDR used the WHO-98 TEF values to establish a Minimal Risk Level (MRL) for dioxin-like compounds.
  - Several state health and environmental agencies currently use the WHO-98 TEF values to evaluate dioxin and furan mixtures (See Table 2, p. 23).

- <u>Practical Considerations</u>: Ecology does not believe that the use of the WHO-98 or WHO-2005 TEF values will significantly increase or decrease the stringency of cleanup requirements established under MTCA. As indicated in Table 1, the two approaches include identical TEF values for 14 of the 17 dioxin and furan congeners. Of the remaining three congeners, the WHO-98 TEF values are lower than the 1989 EPA TEF values for OCDD and OCDF; the WHO-98 TEF value for PeCDD is higher. The WHO-2005 values are also similar to the EPA-1989 values specified in the MTCA rule - TEF values for 12 of the 17 congeners are the same. Of the remaining five congeners, the WHO-2005 TEF values are lower than the 1989 EPA TEF values for four congeners (1,2,3,7,8-PeCDF, 2,3,4,7,8-PeCDF, OCDD and OCDF); the WHO-2005 TEF value for PeCDF is higher. While these differences may affect conclusions on individual samples, Ecology does not believe that the use of the WHO-98 TEF or the WHO-2005 values will significant alter cleanup requirements on a statewide basis (relative to the current rule language).

Cleanup Levels for Dioxin/Furan Mixtures

Issue #2

Should dioxin/furan mixtures be treated as a single hazardous substance or a mixture of multiple hazardous substances when calculating excess cancer risks and determining compliance with cleanup and remediation levels under MTCA?

Background

Ecology amended the MTCA rule in February 2001. Under the rule amendments, a person undertaking a cleanup action may use the Environmental Protection Agency's (EPA, 1989) interim methodology and the toxicity equivalency factor (TEF) values when assessing dioxin and furan mixtures. However, the MTCA rule does not clearly specify how the TEF values should be used within the framework for establishing and evaluating compliance with Method B and C cleanup levels.

After amending the rule, Ecology published a guidance document to explain how to apply the TEF methodology when establishing and evaluating compliance with cleanup levels. These guidance materials are part of a larger guidance document (Cleanup Levels and Risk Calculation (CLARC) (Ecology, 2001). As summarized in Section 2.3, the CLARC guidance describes a process that involves (1) calculating toxic equivalence concentrations for each dioxin and furan congener and (2) adding the toxic equivalence concentrations for all of the congeners to obtain a total toxic equivalence concentration (TEQ) for the mixture. Under the CLARC guidance, the mixture is characterized by the TEQ and treated as a single hazardous substance. The practical implication of this approach is that Method B cleanup levels for the mixture are established at concentrations corresponding to an incremental cancer risk of one-in-one million (1×10^{-6}).

In November 2005, the Rayonier Corporation filed a lawsuit challenging Ecology's interpretation of the MTCA rule provisions related to the use of the TEF methodology. Rayonier argued that (1) each congener should be considered an individual hazardous substance and (2) cleanup levels for each congener should be established at concentrations corresponding to an incremental cancer risk of one-in-one million (1×10^{-6}).

MTCA Rulemaking Options

Ecology has considered three options for resolving this issue:

1. Each Dioxin/Furan Congener Treated as a Single Hazardous Substance: Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one-in-one million (10^{-6}). Cleanup levels for other dioxin and furan congeners would be established by dividing the TCDD cleanup level by the applicable congener-specific TEF. Because there is an overall limit on cancer risk under MTCA of one-in-one hundred thousand (1×10^{-5}), when more than 10 dioxin and furan congeners are present at a site (a likely occurrence), the cleanup levels for TCDD and other individual congeners would need to be adjusted downward to insure this overall risk limitation is not exceeded. If there are multiple pathways of exposure, a further downward adjustment for individual congeners would need to also be made.

2. Dioxin/Furan Mixture Treated as a Single Hazardous Substance: Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one in one million (10^{-6}). The TEF methodology would be used to calculate a TEQ (based on the 17 dioxin/furan congeners identified in Table 1) for environmental samples that would then be compared to TCDD cleanup level.

3. Mixtures of All Dioxin-like Compounds Treated as a Single Hazardous Substance: Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one in one million (10^{-6}). The TEF methodology would be used to calculate a TEQ (based on the 17 dioxin/furan congeners identified in Table 1 and the 12 PCB congeners identified in Table 7) for environmental samples that would then be compared to the TCDD cleanup level.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to state that mixtures of dioxins and furans will be considered a single hazardous substance for purposes of assessing carcinogenic risk and determining compliance with cleanup levels and remediation levels (Option #2). Ecology's rationale for selecting this option includes the following:

- Biological Basis for the TEF Methodology. Option 2 has a sound biological basis in that TEF approach is based on the concept that the various congeners of dioxin/furan essentially act as one chemical, affecting the Ah receptor (aryl hydrocarbon hydroxylase receptor, enzyme induction).

- MTCA Rule Framework: Option 2 is consistent with the overall MTCA rule framework. Specifically:

    - Option 2 is consistent with the approach used to establish, and determine compliance with, the Method A Soil and Ground Water Cleanup Levels for cPAHs currently set forth in the MTCA rule. Those cleanup levels are set forth in Tables 720-1, 740-1, and 745-1 in WAC 173-340-900. See also the footnotes to those cleanup levels.

    - Option 2 is consistent with how Ecology has historically interpreted and applied the MTCA rule to establish, and determine compliance with, Method B and C cleanup levels for mixtures of dioxins and furans and mixtures of cPAHs.

    - Option 2 is consistent with the approach used by other state programs and federal agencies to establish requirements that are applicable or relevant and appropriate under MTCA. Cleanup levels must be at least as stringent as those requirements. See below for examples.

- Other Ecology Programs: Option 2 is consistent with the approaches used by several other Ecology programs when evaluating the health risks associated with dioxin and furan mixtures. These requirements are often ARARs that establish minimum cleanup standards under MTCA. For example:

    - The Water Quality Program used the WHO-98 TEFs when establishing the TMDL for Lake Chelan. In that evaluation, Ecology used congener-specific data to calculate TEQs which were compared with the National Toxics Rule (NTR) criterion for TCDD[11] (Ecology, 2005).

    - The Environmental Assessment Program identified impaired waterbodies by comparing the TEQs for dioxins/furans to the NTR criteria for TCDD. (Ecology, 2004).

    - The Hazardous Waste & Toxics Reduction Program specifies that fertilizers must contain no more than eight parts per trillion of dioxin, measured as toxic equivalent (TEQ).

    - The Air Quality Program uses the TEF methodology to calculate TEQs for potential emissions from proposed new sources of dioxins/furans. The TEQ values are compared to a screening level for mixtures of

[11] The NTR criterion for TCDD is based on a 10^{-6} cancer risk level.

dioxin/furans that is expressed in terms of TCDD. The screening level is based on an incremental cancer risk of one-in-one million (WAC 173-460-060).

- Consistency With Ecology's Initiatives on Toxic Chemicals: Public concerns about health threats posed toxic chemicals have grown over the last decade as new information on toxicity and body burdens have become available. Ecology has undertaken several initiatives to reduce and cleanup sources of toxic chemicals in Puget Sound and other parts of the state. Options 2 and 3 reflect risk policy choices that are consistent with public concerns and the high priority assigned to these initiatives.

- Approaches Used by EPA and Other Federal and International Agencies: The EPA Drinking Water Program has established a Maximum Contaminant Level (MCL) for TCDD and evaluates compliance based on that congener. However, Option 2 is consistent with the approaches used by several federal and international agencies when evaluating the health risks associated with dioxin/furan mixtures. For example:

  - EPA (1998) published a guidance memo for cleanup of dioxin-contaminated properties. The guidance specifies that compliance should be evaluated by comparing the 1 ppb cleanup standard to TEQs calculated from information on 17 dioxin/furan congeners.

  - EPA has published human health water quality criteria for TCDD in the NTR (EPA, 1992) and the California Toxics Rule (EPA, 2000). In promulgating the California Toxics Rule, EPA stated that when water quality-based effluent limits are established for dioxin or dioxin-like compounds, those limits should be expressed using a TEQ approach (65 FR 31682 at 31695).

  - EPA established emission limits for medical waste incinerators that include limitations expressed in terms of either (1) allowable levels of total chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans or (2) allowable TEQs. The proposed rule for primary manganese refining facilities also includes emission limits for dioxin/furan mixtures expressed in terms of ng of toxic equivalents (TEQ) per dry standard cubic meter.

  - ATSDR (1998) established a Minimal Risk Level (MRL) for dioxin and dioxin-like compounds at a concentration of 1 pg TEQ/kg-day.

  - The World Health Organization has established a tolerable daily intake of 1-4 pg TEQ/kg-day.

  - The FDA uses the TEF methodology and TEQs to monitor food and animal feed with the goal of reducing dietary exposure to dioxin-like compounds (FDA, 2005).

- Other State Environmental Programs: The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) recently completed a survey of state screening levels and action levels (ASTSWMO, 2006). They found that "...[t]he cancer risk basis of the standards and guidelines reported by States ranged from a stringent one-in-ten million (1E-07) to one-in-ten thousand (1E-04). The majority of standards utilize the more typical one-in-one million (1E-06) risk level criteria...." Ecology reviewed the webpages of several environmental agencies in other states to determine whether agencies were treating dioxin/furan mixtures as a single hazardous substance (Option 2) or a mixture of multiple hazardous substances (Option 1). Initial results are shown in Table 2 on the following page. While it is sometimes difficult to interpret some of the regulatory provisions, the initial results[12] indicate that many (but not all) states use approaches that are consistent with Option 2 (i.e. establish cleanup levels and/or criteria for TCDD and then use the TEQ for the mixture to evaluate compliance with those cleanup levels and/or criteria). One exception is the Oregon Superfund program which uses an approach similar to Option 1.

[12] Ecology has not surveyed all 50 states and, consequently, recognizes that the results may not reflect the full range of approaches used by different state agencies and/or the variability among programs within a single state agency

Table 2: Comparison of Approaches Used By Other State Environmental Agencies When Evaluating Dioxin/Furan Mixtures

State	Environmental Program	TEF Values	Regulatory Approach	Risk Level applicable to mixture
Florida[13]	Superfund	WHO-98	Option 2	10^{-6}
Minnesota[14]	Pollution Control Agency	WHO-98	Option 2	10^{-5} (includes PCBs)
New York[15]	Water Quality	EPA-89	Option 2	10^{-5}
Oregon[16]	Waste Mgt & Cleanup	WHO-98	Option 1	10^{-5}
Oregon[17]	Water Quality	WHO-98	Option 2	10^{-6}
Texas[18]	Superfund	WHO-98	Option 2	10^{-5} (includes PCBS)
Wisconsin[19]	Superfund	EPA-89	Option 2	10^{-6}

- Consideration of Multiple Substances and Multiple Pathways: Treating dioxin/furan mixtures as a single hazardous substance minimizes the need for such adjustments and simplifies the process for establishing cleanup levels. The MTCA Cleanup Regulation specifies that Method B and C cleanup levels established for individual hazardous substances based on a particular pathway (e.g. soil ingestion) must be adjusted downward to take into account exposure to multiple hazardous substances and/or multiple exposure pathways in situation where total excess cancer risk would exceed 10^{-5}.

[13] FloridaTechnical Report: Development of Cleanup Target Levels (CTLs) For Chapter 62-777, Florida AdministrativeCode, Prepared for the Division of Waste Management Florida Department of Environmental Protection By Center for Environmental & Human Toxicology, University of Florida, Gainesville, Florida, February, 2005, Table 19, Page 61;
[14] Minnesota Pollution Control Agency, Site Remediation Section. Draft Guideline: Risk-Based Guidance for the Soil-Human Health Pathway Vol. 2 Technical Support Document Section 8.2.4. Calculation Spreadsheet: Tier 1 SRV Spreadsheet; Risk-tier1srv.xls, 01/06
[15] New York State Department of Environmental Conservation Rules and Regulations, 6NYCRR Part 703, Surface Water and Groundwater Quality Standards and Groundwater Effluent Limitations, Table 1
[16] Oregon Department of Environmental Quality, Waste Management & Cleanup Division. Policy on Toxicity Equivalency Factors. And Electronic Correspondence with Oregon DEQ M. Paulsen to McCormack, March 2006.
[17] Oregon Department of Environmental Quality, Toxic Compounds Criteria, 1999-2003 Water Quality Standards Review Draft Issue Paper, Section 2.3.
[18] Texas Commission on Environmental Quality, Texas Risk Reduction Program, Development of Protective Concentration Levels. Rule §350.76 Approaches for Specific Chemicals of Concern to Determine Human Health Protective Concentration Levels.
[19] Wisconsin Department of Natural Resources.

Choice of TEF Values for cPAH Mixtures

Issue # 3

When characterizing the carcinogenic risks of cPAH mixtures, should Ecology use the RPF/TEF values in the 2005 California EPA Guidance Document?

Background

Polycyclic Aromatic Hydrocarbons (PAHs) are a group of chemicals formed during the incomplete burning of organic materials such as wood, garbage, oil, coal, gas, tobacco, and charbroiled meat. There are more than 100 different PAHs.

EPA (1993) published provisional guidance for evaluating the carcinogenic risks associated with PAH mixtures using a relative potency factor (RPF) approach. The EPA (1993) approach uses benzo(a)pyrene [BaP] as the index chemical (i.e., having a relative potency of 1.0) and includes RPF values for seven (7) carcinogenic PAHs.

The California Environmental Protection Agency (Cal EPA, 1994) expanded upon the EPA approach when it developed Potency Equivalency Factors (PEFs) for use in evaluating PAH mixtures. The Cal EPA approach also uses BaP as the index chemical and includes PEFs for twenty-two (22) carcinogenic PAHs[20].

The California EPA recently completed a review of the 1994 PEF values. Based on that review, Cal EPA published an update list of PEF values (Cal EPA, 2005). The Cal EPA (2005) approach continues to use BaP as the index chemical and includes PEFs for twenty-five (25) carcinogenic PAHs. Table 3 summarizes the PAH compounds and RPF/PEF values in the three approaches (i.e. EPA, 1993; Cal EPA, 1994; and Cal EPA, 2005).

MTCA Rulemaking Options

Ecology has considered two options for resolving this rulemaking issue:

1. Cal-EPA 1994 Values: Under this option, Ecology would continue to use the PEF values from the 1994 California Environmental Protection Agency's guidance document;
2. Cal-EPA 2005 Values: Under this option, Ecology would revise the MTCA rule to specify that the updated PEF values (Cal EPA 2005) should be used when assessing PAH mixtures.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to specify that the PEF values and methodology described in Cal EPA (2005) should be used when assessing the carcinogenic risk of PAH mixtures (Option #2). Ecology's rationale for selecting this option includes the following:

[20] In 2001, Ecology amended the MTCA rule to explicitly authorize cleanup proponents to use the Cal EPA (1994) methodology to evaluate the toxicity and assess the risks from exposure to carcinogenic PAH mixtures

- Scientific and Biological Basis: Polycyclic aromatic hydrocarbons are a well defined group of chemicals consisting of three or more fused aromatic rings. PAHs are ubiquitous multi-media contaminants commonly found as complex environmental mixtures. The carcinogenicity of PAHs is due to the generation of biologically active metabolites which covalently bind to DNA and is considered a common mode of action for all cPAHs (EPA, 1993; Naz, 1999). Cal EPA (2005) considered the most recent scientific information evaluating individual tumorigenic responses for 25 cPAHs when updating the PEF values. When preparing the 2001 rule amendments, Ecology concluded that Cal-EPA (1994) values had broader applicability than the EPA (1993) values:

  > *EPA's TEFs are all based on dermal studies which is good for internal relative ranking but may not be good for applying to ingestion or inhalation exposures. In fact, EPA explicitly cautions against applying their TEFs to inhalation exposures. Instead, EPA proposes that their TEFs be applied only to ingestion exposure and is silent on the issue of dermal exposure (which is surprising, since their TEFs are based on mouse skin painting). In contrast, CalEPA TEFs are based on a variety of exposure routes, including a drinking water study for dibenzo(a,h)anthracene (Snell and Stewart, 1962), an intrapulmonary study for benzo(k)fluoranthene (Deutsch-Wenzel et al, 1983), and a skin painting study for chrysene (Wynder and Hoffman, 1959). In general, CalEPA TEFs were based on tumor data from relevant exposure routes (i.e., intrapulmonary and intratracheal administration, since CalEPA TEFs were targeted at air contaminants), tumor data from other exposure routes, genotoxicity data, and structure-activity relationships (SARs), in that order. Because CalEPA TEFs were based on a broader array of carcinogenic endpoints, these appear to have more general applicability (e.g., for route to route extrapolation) than EPA's approach based on a single endpoint. (Ecology SAB Briefing Memorandum, 1998)*

- Scientific Review: The MTCA Science Advisory Board reviewed and endorsed Ecology's use of the original Cal-EPA values during the 2001 rulemaking process. Ecology believes that the use of the updated Cal-EPA values is a logical extension of the initial decision to use the original Cal-EPA values. Ecology intends to ask the MTCA Science Advisory Board to review this issue prior to publishing final rule amendments.

- Similarity to PEF Values Used Under the Current MTCA: The updated Cal-EPA values are similar to PEF values in 1994 Cal-EPA guidance materials. As indicated in Table 3, the 1994 and 2005 Cal-EPA approaches include identical PEF values for six of the seven cPAHs typically assessed at cleanup sites. The exception is dibenzo(a,h)anthacene which has a smaller PEF in the updated guidance. While this difference may impact conclusions on individual samples, Ecology does not believe that the use of the more current PEF values will significantly alter the stringency of cleanup requirements on a statewide basis.

- Environmental Protection Agency and Other State Programs: EPA and most other state environmental agencies use the EPA (1993) values when evaluating the health risks of PAH mixtures. However, the Cal-EPA approach is conceptually similar to the EPA approach and scientists at EPA-Region 10 agree that the most current California EPA's PEFs provide a scientifically valid way to evaluate the health risks associated with exposures to PAH mixtures.

Table 3: Comparison of Relative Potency Factors (RPFs) and Potency Equivalency Factors (PEFs) for Polycyclic Aromatic Hydrocarbons			
Polycyclic Aromatic Hydrocarbon	**Relative Potency Factors (RPF) (EPA, 1993[21])**	**Potency Equivalency Factors (PEF) (Cal-EPA, 1994[22]) (Current MTCA)**	**Potency Equivalency Factors (PEFs) (Cal-EPA, 2005[23]) (Planned Revisions)**
Benzo(a)pyrene	1	1	1
Benz(a)anthracene	0.1	0.1	0.1
Benz(b)fluoranthene	0.1	0.1	0.1
Benz(j)fluoranthene	------------------	0.1	0.1
Benz(k)fluoranthene	0.01	0.1	0.1
Dibenz(a,j)acridine	------------------	0.1	0.1
Dibenz(a,h)acridine	------------------	0.1	0.1
7H-dibenzo(c,g)carbazole	------------------	1.0	1.0
Dibenzo(a,e)pyrene	------------------	1.0	1.0
Dibenzo(a,h)pyrene	------------------	10	10
Dibenzo(a,i)pyrene	------------------	10	10
Dibenzo(a,l)pyrene	------------------	10	10
Indeno(1,2,3-cd)pyrene	0.1	0.1	0.1
5-methylchrysene	------------------	1.0	1.0
1-nitropyrene	------------------	0.1	0.1
4-nitropyrene	------------------	0.1	0.1
1,6-dinotropyrene	------------------	10	10
1,8-dinotropyrene	------------------	1.0	1.0
6-nitrochrysene	------------------	10	10
2-nitrofluorene	------------------	0.01	0.01
Chrysene	0.001	0.01	0.01
Dibenz(a,h)anthracene	1	0.4	0.1
7,12-dimethylbenzanthracene	------------------	-------------------	10
3-methylcholanthrene	------------------	-------------------	1
5-nitroacenaphthene	------------------	-------------------	0.01

21 U.S. EPA, 1993. Provisional Guidance for Quantitative risk Assessment of Polycyclic Aromatic Hydrocarbons. July 1993. EPA/600/R-93/089.

22 Cal-EPA, 1994. Benzo(a)pyrene as a toxic air contaminant. Part B: Health Assessment, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Berkeley, California

23 Cal-EPA, 2005. Air Toxics Hot Spots Program Risk Assessment Guidelines, Part II Technical Support Document for Describing Available Cancer Potency Factors. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. May 2005. Pages B-77 to B-97.

Range of PAH Compounds Used to Characterize cPAH Mixtures

Issue # 4

When characterizing the carcinogenic risks of cPAH mixtures, should Ecology continue to focus on the seven PAH compounds identified in the current MTCA rule?

Background

EPA (1993) published provisional guidance for evaluating the carcinogenic risks associated with PAH mixtures using a relative potency factor (RPF) approach. The EPA (1993) approach uses benzo(a)pyrene [BaP] as the index chemical (i.e., having a relative potency of 1.0) and includes RPF values for seven (7) carcinogenic PAHs (See Table 4).

Cal EPA (1994) expanded upon the EPA approach when it developed Potency Equivalency Factors (PEFs) for use in evaluating PAH mixtures. The Cal EPA approach also uses BaP as the index chemical and includes PEFs for twenty-two (22) carcinogenic PAHs. The updated Cal-EPA guidance materials (Cal EPA, 2005) includes PEFs for twenty-five (25) carcinogenic PAHs.

WAC 173-340-708(8)(e) specifies that, at a minimum, seven cPAH[24] compounds (benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene) must be evaluated when using the TEF approach to characterize cPAH mixtures. However, the rule also states that Ecology may require other compounds from the Cal-EPA list to be evaluated at individual sites. To date, Ecology has not required other cPAH compounds to be evaluated at individual sites.

Table 4: cPAH Compounds Included in California EPA 2005 Guidance

cPAHs Listed in MTCA Rule	TEF	Other cPAHs on Cal-EPA List	TEF
benzo[a]pyrene	1	benzo(j)fluoranthene	0.1
benzo[a]anthracene	0.1	dibenz[a,j]acridine	0.1
benzo[b]fluoranthene	0.1	dibenz[a,h]acridine	0.1
benzo[k]fluoranthene	0.1	7H-dibenzo[c,g]carbazole	1
chrysene	0.01	dibenzo[a,e]pyrene	1
dibenz[a,h]anthracene	0.1	dibenzo[a,h]pyrene	10
indeno[1,2,3-cd]pyrene	0.1	dibenzo[a,i]pyrene	10
		dibenzo[a,l]pyrene	10
		5-methylchrysene	1
		1-nitropyrene	0.1
		4-nitropyrene	0.1
		1,6-dinitropyrene	10
		1,8-dinitropyrene	1
		6-nitrochrysene	10
		2-nitrofluorene	0.01
		7,12-dimethylbenzanthracene[a]	10
		3-methylcholanthrene	1
		5-nitroacenaphthene	0.01

[24] WAC 173-340-200 includes the following definition: “PAHs (carcinogenic)” or “cPAHs” means those polycyclic aromatic hydrocarbons substances, PAHs, identified as A (known human) or B (probable human) carcinogens by the United States Environmental Protection Agency. These include benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene.”

MTCA Rulemaking Options

Ecology has considered three options for resolving this rulemaking issue:

1. EPA List: Under this option, Ecology would revise WAC 173-340-708(8)(e)(ii) to state that PAH mixtures must be characterized using the seven PAH compounds listed in the definition of "carcinogenic PAHs".
2. Current Rule Language: Under this option, Ecology would continue to use the current rule language which states that, at a minimum, analyses and TEF calculations must be based on the seven PAH compounds identified in the definition of "PAH (carcinogenic)" with Ecology retaining the discretion to require an evaluation of additional compounds at individual sites.
3. CAL-EPA List: Under this option, Ecology would revise WAC 173-340-708(8)(e)(ii) to state that PAH mixtures must be characterized using the twenty-five PAH compounds listed in the California EPA guidance.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to continue to use the current language in WAC 173-340-708(8) which states that, at a minimum, analyses and TEF calculations must be based on the seven PAH compounds identified in the definition of "PAH (carcinogenic)" with Ecology retaining the discretion to require an evaluation of additional compounds at individual sites (Option 2). Ecology's rationale for selecting this option includes the following:

- Biological Basis: Polycyclic aromatic hydrocarbons are a well-defined group of chemicals consisting of three or more fused aromatic rings. The carcinogenicity of PAHs is due to the generation of biologically active metabolites which covalently bind to DNA and is considered a common mode of actions for all cPAHs (EPA, 1993; Naz, 1999). EPA has identified seven (7) PAH[25] compounds as A (known human) or B (probable human) carcinogens[26]. The National Toxicology Program (NTP, 2005) have identified 15 PAH compounds as "reasonably anticipated to be a human carcinogen". Cal EPA considered the most recent scientific information evaluating individual tumorigenic responses for 25 cPAHs when updating the PEF values for cPAHs (Cal EPA, 2005).

- Current MTCA Rule and Implementation Experience: WAC 173-340-708(8)(e) specifies that, at a minimum, seven cPAH[27] compounds must be evaluated when using the TEF approach to characterize cPAH mixtures. However, the rule also states that Ecology may require other compounds from the Cal-EPA list to be evaluated at individual sites. To date, Ecology has not required other cPAH compounds to be evaluated at individual sites.

- Other Environmental Programs: Ecology reviewed the methods and procedures used by other environmental programs to characterize PAH mixtures. Several Ecology programs[28] [29]consider more

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[25] These include benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene.

[26] On March 29, 2005, EPA issued "Guidelines for Carcinogen Risk Assessment" which replaced the 1986 risk guidelines. The 2005 guidelines include a new set of weight of evidence descriptors that replace the previous system (A, B1, B2, C and D).

[27] WAC 173-340-200 includes the following definition: "PAHs (carcinogenic)" or "cPAHs" means those polycyclic aromatic hydrocarbons substances, PAHs, identified as A (known human) or B (probable human) carcinogens by the United States Environmental Protection Agency. These include benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene."

[28] The Hazardous Waste Program. Polycyclic aromatic hydrocarbons are designated dangerous wastes based on persistence criteria consistent with WAC 173-303-100 (6). For the purposes of Chapter 173-303 WAC, the PAHs of

than the seven PAH compounds identified in EPA (1993) when evaluating PAH mixtures. However, it appears that most state and federal environmental agencies focus on the seven PAH compounds when evaluating carcinogenic risks. For example:

- The Air Quality Program focuses on the seven PAH compounds identified in EPA (1993) when evaluating new source emissions under Chapter 173-460 WAC (Controls For New Sources Of Toxic Air Pollutants).
- EPA's Superfund Program generally uses the methods and procedures described in EPA (1993) when evaluating health risks associated with PAH mixtures.
- Ecology reviewed the methods and procedures used by several other state superfund programs. Based on that review, most states appear to be using the EPA (1993) methodology and focus their evaluation on the seven cPAHs identified in the EPA document. (See Table 5, page ___)

- Practical Considerations. Standard analytical methods are not available to analyze the levels of many of the PAH compounds included on the Cal-EPA list.

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concern for designation include a large suite of PAHs[28]. A person whose waste contains PAHs as defined in WAC 173-303-040, must determine the total PAH concentration by summing the concentration percentages of each of the polycylic aromatic hydrocarbons for which they know the concentrations (Ecology, 1998b). The equivalent concentration percentage is the sum of all the concentration percentages for a particular toxic category, such as halogenated organic compounds or PAHs.

[29] Ecology considers 16 PAH compounds when evaluating compliance with the Sediment Management Standards (Chapter 173-204 WAC). PAH concentrations were reported on a weight-weight basis (ug/kg wet weight or mg/kg dry weight) for each individual low and high molecular weight PAH and then added together to reflect the total concentration for low and high molecular weight PAHs . Low molecular weight PAHs, LPAH: naphthalene, 2-methylnaphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene; High molecular weight PAHs, HPAH: fluroanthene, pyrene, benzo(a)anthracene, chrysene, bewnzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, indeno(1,2,3-cd)pyrene, dibenzo(a,H)anthracene, benzo(ghi)perylene

Cleanup Levels for cPAH Mixtures

Issue # 5

Should PAH mixtures be treated as a single hazardous substance or a mixture of multiple hazardous substances when calculating excess cancer risks and determining compliance with cleanup and remediation levels under MTCA?

Background

Ecology amended the MTCA Cleanup Regulation in February 2001. Under the rule amendments, a person undertaking a cleanup action may use the California EPA (1994) methodology and potency equivalence factors (PEFs) when assessing PAH mixtures. However, the MTCA rule does not clearly specify how the PEF values should be used within the framework for establishing and determining compliance with Method B and C cleanup levels.

After amending the rule, Ecology published a guidance document to explain how to apply the Cal EPA (1994) methodology when establishing cleanup levels. These guidance materials are part of the CLARC guidance (Ecology, 2001). As summarized in Section 2.3, the CLARC guidance describes a process that involves (1) calculating toxic equivalence concentrations for each PAH compound and (2) adding the toxic equivalence concentrations for all of the compounds to obtain a total toxic equivalence concentration (TEQ) for the mixture. Under the CLARC guidance, the mixture is characterized by the TEQ and treated as a single hazardous substance. The practical implication of this approach is that Method B cleanup levels for the mixture are established at concentrations corresponding to an incremental cancer risk of one-in-one million (1×10^{-6}).

In November 2005, the Rayonier Corporation filed a lawsuit challenging Ecology's interpretation of the MTCA rule provisions related to the use of the TEF methodology for dioxins and furans. Rayonier's arguments related to dioxin/furan mixtures could also be applied to PAH mixtures and would result in an approach where (1) each PAH compound would be considered an individual hazardous substance and (2) cleanup levels for each PAH compound would be set at concentrations corresponding to an incremental cancer risk of one-in-one million (1×10^{-6}).

MTCA Rulemaking Options

Ecology has considered two options for resolving this issue:

1. Each PAH Compound Treated as a Single Hazardous Substance: Under this option, Method B cleanup levels would be established for B(a)P based on an incremental cancer risk of one-in-one million (10^{-6}). Cleanup levels for other PAH compounds would be established by dividing the B(a)P cleanup level by the applicable TEF. Because there is an overall limit on cancer risk under MTCA of one-in-one hundred thousand (1×10^{-5}), when more than 10 carcinogenic PAHs and other carcinogens are present at a site, the cleanup levels for B(a)P and other carcinogenic PAHs would need to be adjusted downward to insure this overall risk limitation is not exceeded. If there are

multiple pathways of exposure, a further downward adjustment for carcinogenic PAHs would also need to be made.

2. Mixture Treated as a Single Hazardous Substance: Under this option, Method B cleanup levels would be established for B(a)P based on an incremental cancer risk of one-in-one million ($1 X 10^{-6}$). The PEF values in Cal-EPA (2005) would be used to calculate a TEQ (based on the 7 PAH compounds identified in Table 3) for environmental samples that would then be compared to the B(a)P cleanup level.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to state that mixtures of cPAHs will be considered a single hazardous substance for purposes of assessing carcinogenic risk and determining compliance with cleanup levels and remediation levels (Option 2). Ecology's rationale for selecting this option includes the following:

- Biological Basis: Polycyclic aromatic hydrocarbons are a well defined group of chemicals consisting of three or more fused aromatic rings. The carcinogenicity of PAHs is due to the generation of biologically active metabolites which covalently bind to DNA and is considered a common mode of actions for all cPAHs (EPA, 1993; Naz, 1999). The TEF methodology is, in part, based on the cPAHs collectively producing a similar biological response, cancer, acting as one chemical through a common mode of action. Cal EPA (2005) considered the most recent scientific information evaluating individual tumorigenic responses for 25 cPAHs when updating the PEF values for cPAHs.

- Approach Used by Ecology Under MTCA: Ecology has historically considered mixtures of dioxins/furans, cPAHs or PCBs as single hazardous substances when setting Method B and Method C cleanup levels. Option 2 is also consistent with the policies and procedures underlying the Method A soil cleanup levels[30].

- Other Ecology Programs: In contrast to dioxins/furans and PCBs, there more variability in the approaches used by other programs to evaluate/regulate PAH mixtures. Several Ecology programs currently evaluate compliance with requirements for individual PAH compounds using approaches similar to Option 1. For example:

  - The National Toxics Rule establishes surface water standards based on protection of human health. The NTR includes individual criteria for seven PAH compounds. Compliance is evaluated separately for each PAH compound.

  However, other Ecology programs have adopted approaches that are similar to Option 2. For example:

  - The Air Quality Program treats PAH mixtures as a single toxic air pollutant when evaluating potential emissions from proposed new sources. Under this regulation, PAH emissions are compared to screening levels for mixtures of PAHs that are expressed in terms of B(a)P[31]. The screening levels are based on an incremental cancer risk of one-in-one million (WAC 173-460-060).

  - The Water Quality Program has established a ground water criterion for both PAHs and BaP (Chapter 173-200 WAC).

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[30] When developing the Method A values, cPAH mixtures were treated as a single hazardous substance and the Method A soil cleanup level was calculated using a target cancer risk of one-in-one million (10^{-6})

[31] For mixtures of PAHs, WAC 173-460-050 states "The owner or operator of a source that may emit a mixture of polyaromatic hydrocarbon emissions shall quantify the following PAHs and shall consider them together as one TAP equivalent in potency to benzo(a)pyrene: benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, chrysene, dibenzo(a,h,)anthracene, indenol(1,2,3-cd)pyrene, benzo(a)pyrene." [WAC 173-460-050 (4) (iii) (c)].

- Consistency With Ecology's Initiatives on Toxic Chemicals: Public concerns about health threats posed toxic chemicals have grown over the last decade as new information on toxicity and body burdens have become available. Ecology has undertaken several initiatives to reduce and cleanup sources of bioaccumulative chemicals in Puget Sound and other parts of the state. Selection of an option that relaxes cleanup requirements for chemical mixtures (Option 1) would be inconsistent with these Ecology initiatives.

- Approaches Used by EPA and Other Federal and International Agencies: There is also a great deal of variability in the approaches used by federal programs to evaluate/regulate PAH mixtures. EPA has established a maximum contaminant level (MCL) for BaP (0002 mg/L) and compliance is evaluated based on BaP measurements in drinking water. However, several federal programs implement approaches that are similar to Option 2. For example:

    - The EPA Superfund program continues to use the methods and procedures described in EPA (1993) and has reaffirmed the use of TEF methodology for cPAHs considered as a single hazardous substance for the whole mixture by summing the carcinogenic potential of individual PAHs relative to an index compound (e.g., benzo(a)pyrene)[32].

    - EPA established emission limits for polycyclic organic matter, PAHs, as part of its list of 189 hazardous air pollutants using TEF methodology to evaluate the potential health risks from exposures to airborne particulate mater contaminated with PAHs.

- Varying Approaches Used by State Environmental Programs. The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) recently completed a survey of state screening levels and action levels (ASTSWMO, 2006). They found that "...[t]he cancer risk basis of the standards and guidelines reported by States ranged from a stringent one-in-ten million (1E-07) to one-in-ten thousand (1E-04). The majority of standards utilize the more typical one-in-one million (1E-06) risk level criteria...." Ecology reviewed the webpages of several environmental agencies in other states to determine whether agencies were treating PAH mixtures as a single hazardous substance (Option 2) or a mixture of multiple hazardous substances (Option 1). Initial results are shown in Table 5 on the following page. While it is sometimes difficult to interpret some of the regulatory provisions, the initial results indicate that two states treat PAH mixtures as single hazardous substances when establishing those requirements. However, the majority of states surveyed by Ecology consider each PAH compound as an individual hazardous substance (Option 1).[33]

- Consideration of Multiple Substances and Multiple Pathways: Treating PAH mixtures as a single hazardous substance minimizes the need for such adjustments and simplifies the process for establishing cleanup levels. The MTCA Cleanup Regulation specifies that Method B and C cleanup levels established for individual hazardous substances based on a particular pathway (e.g. soil ingestion) must be adjusted downward to take into account exposure to multiple hazardous substances and/or multiple exposure pathways in situation where total excess cancer risk would exceed 10^{-5}.

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[32] Lynn Flowers, Abstract:Toxicology of Polycyclic Aromatic Hydrocarbon (PAH) Mixtures. IRIS Staff, US Environmental Protection Agency. Presentation from Spring 2005 Society of Toxicology Meeting.

[33] Ecology has not surveyed all 50 states and, consequently, recognizes that the results may not reflect the full range of approaches used by different state agencies and/or the variability among environmental programs within a single state agency.

Table 5: Comparison of Approaches Used By Other State Environmental Agencies When Evaluating PAH Mixtures

State	State Programs	TEF Value	Each PAH = Single Substance (Option 1)	Mixture = Single Substance (Option 2)	Cancer Risk Level Applied to PAHs
Florida[34]	Waste Management Div.	EPA 1993	X		$1x10^{-6}$
New Jersey[35]	Site Remediation Program	EPA 1993	X		$1x10^{-6}$
Idaho[36]	Waste Mngmt & Remed.	EPA 1993	X		$1x10^{-6}$
Louisiana[37]	Remediation Service Div.	EPA 1993	X		$1x10^{-6}$
Massachusetts[38]	MA Dept. of Env. Prot.	EPA 1993	X		$1x10^{-6}$
Minnesota[39]	Pollution Control Agency	Cal-EPA		X	$1x10^{-5}$ (mixture)
Oregon[40]	Oregon DEQ	EPA 1993	X		$1x10^{-6}$
Texas[41]	Remediation Division	EPA 1993	X		$1x10^{-5}$
Wisconsin[42]	Dept. of Nat. Resources	EPA 1993	X	X[43]	$7x10^{-7}$ (mixture)

[34] Technical Report: Development of Cleanup Target Levels (CTLs) For Chapter 62-777, F.A.C., Prepared for the Division of Waste Management Florida Department of Environmental Protection By Center for Environmental & Human Toxicology, University of Florida, Gainesville, Florida, February, 2005, Table 19, Page 61; and Table 1: Technical Reports: page 4 of 41

[35] Site remediation Program; contact Linda Cullen (609-984-9778

[36] Idaho Risk Evaluation Manual, Final, July 2004; RBCA Tier 2 Software version 1.0, user's guide and Risk-based Corrective Action for Tier 2 Evaluation.

[37] LDEQ RECAP 2003; APPENDIX D: GUIDELINES FOR ASSESSING POLYCYCLIC AROMATIC HYDROCARBONS POLYCHLORINATED DIBENZODIOXINS/POLYCHLORINATED DIBENZOFURANS

[38] Massachusetts Department of Environmental Protection. Polycyclic Aromatic Hydrocarbons (PAHs). Guidance for Disposal Site Risk Characterization.

[39] Minnesota Department of Health. Risk Assessment Rules/Guidance. Polycyclic Aromatic Hydrocarbons:Methods for Estimating Health Risks from Carcinogenic PAHs. And Risk-Based Guidance for The Soil-Human Health Pathway. Volume 2. Technical support document Minnesota Pollution control Agency. Site Remediation Section, January 1999, page 53. Calculation Spreadsheet: Tier 1 SRV Spreadsheet; Risk-tier1srv.xls, 01/06.

[40] Oregon Department of Environmental Quality. E-Mail From M. Poulsen (OR DEQ) to Dr. M. Bailey (EPA, Region X) March 30, 2006; and email from Michael Anderson (Michael.R.ANDERSON@state.or.us; OR DEQ) to Ecology Staff on June 27, 2006.

[41] Texas Natural Resource Conservation Commission; Chapter 350 – Texas Risk Reduction Program; SUBCHAPTER D : DEVELOPMENT OF PROTECTIVE CONCENTRATION LEVELS; §§350.71 - 350.79; September 23, 1999 page 89; and TNRCC Regulatory Guidance Remediation Division: RG-366/TRRP-18; Risk Levels, Hazard Indices, and Cumulative Adjustment; August 2002

[42] Wisconsin Department of Natural Resources. Soil Cleanup Levels for Polycyclic Aromatic Hydrocarbons (PAHs) Interim Guidance. Publication RR-519-97, April 1997.

[43] The Wisconsin DNR Interim Guidance specifies that cleanup proponents may develop soil cleanup levels based on BaP equivalent concentrations as an alternative to applying generic residual contamination levels (RCLs).

Use of the TEF Methodology for PCBs Mixtures

Issue # 6

Should Ecology amend the MTCA rule to explicitly allow or require the use of the WHO-98 TEF values and methodology to assess the carcinogenic risks of PCB mixtures?

Background

Polychlorinated biphenyls (PCBs) are a group of synthetic organic chemicals that include 209 individual chlorinated biphenyl compounds (known as congeners). Commercial mixtures of PCBs were manufactured in the United States from @ 1930 to 1977 under the trademark "**Aroclor**" followed by a four digit number; usually the first two digits indicate the parent biphenyl molecule and the last two digits indicate the percent chlorine by weight[44]. PCBs were used as coolants and lubricants in electrical equipment, such as capacitors and transformers, because of their inflammability, chemical stability, and insulating properties. There are no known natural sources of PCBs.

There are two general approaches for evaluating health risks associated with environmental concentrations of PCBs:

- Total PCB Concentrations: Under the MTCA Cleanup Regulation, excess cancer risks, cleanup levels and remediation levels for PCB mixtures are currently calculated using the cancer slope factor for PCBs published in the Integrated Risk Information System (IRIS) database. Compliance is evaluated using measurements of total PCB concentrations in environmental media using standard methods (e.g. EPA Methods 8080 and 8081) that involve the use of gas chromatography/electron capture detection systems. Specifically, total PCB concentrations are estimated by comparing the chromatographic pattern of peaks in the environmental sample with the pattern or number of peaks in a commercial Arochlor sample.

- Congener-specific analyses: PCB mixtures may include up to 209 individual congeners which differ in terms of the number and location of chlorine atoms. Over the last 30 years, the standard approach for estimating PCB environmental concentrations has begun to shift from the analysis of commercial mixtures to congener-based analyses. There is a now sizable body of scientific information supporting the use of a TEF methodology to characterize PCB mixtures. EPA (1991)[45] concluded that selected PCBs may share a common mode of action with TCDD. Ahlborg et al. (1994)[46] concluded that TEFs are applicable to certain PCBs that display dioxin-like properties because they share a common mode of action with TCDD. In 1998, the World Health Organization (WHO)-European Center for

[44] For example, Aroclor 1260 contains 12 carbon atoms (parent biphenyl molecule) and approximately 60 percent chlorine by weight. Aroclor 1016 is an exception to this nomenclature scheme, as it contains 12 carbon atoms and contains over 41 percent chlorine by weight.

[45] U.S. EPA. 1991. Workshop report on toxicity equivalency factors for polychlorinated biphenyl congeners. Risk Assessment Forum. EPA/625/3-91/020. The purpose of the 1991 EPA workshop was to examine the existing toxicity and exposure database on PCBs to ascertain the feasibility of developing toxicity equivalency factors for dioxin-like PCB congeners.

[46] Ahlborg UG, Becking GC, Birnbaum LS, Brouwer A, Derks HJGM, Feeley M, Golor G, Hanberg A, Larsen JC, Liem AKD, et al. 1994. Toxic equivalency factors for dioxin-like PCBs; report on a WHO-ECEH and IPCS consultation. Chemosphere 28 (6): 1049-1067. The results of the 1991 EPA workshop were published in this peer-reviewed technical publication

Environmental Health and the International Program on Chemical Safety generated a database consisting of approximately 1,200 peer-reviewed publications evaluating the toxicity of PCBs. Based on that review, the WHO proposed TEF values for 12 dioxin-like PCBs (Van den Berg et al., 1998)[47]. Table 7 summarizes the WHO-98 TEF values for 12 coplanar PCB congeners and compares those values with the earlier WHO-94 values.

MTCA Rulemaking Options

Ecology has considered three options for resolving this rulemaking issue:

1. Require Evaluation of Dioxin-Like PCB Congeners: Under this option, Ecology would revise the MTCA Cleanup Regulation to require that excess cancer risks, cleanup levels and remediation levels for PCB mixtures be calculated using the WHO-98 TEF values and methodology recommended by the World Health Organization (Van den Berg et al. 1998);
2. Provide Option to Evaluate Dioxin-Like PCB Congeners: Under this option, Ecology would revise the MTCA Cleanup Regulation to provide the option for calculating excess cancer risks, cleanup levels and remediation levels for PCB mixtures using the WHO-98 TEF values and methodology recommended by the World Health Organization (Van den Berg et al. 1998). [The WHO convened a meeting of scientific experts in June 2005 to re-evaluate the 1998 TEF values. The results of the June 2005 meeting are presented in Van den Berg et al. (2006)[48]. This information was published after Ecology distributed draft rule language for public review.];
3. Defer Issue to Future Rulemaking Process: Under this option, Ecology would defer this issue to a subsequent rulemaking and continue to calculate excess cancer risk, cleanup levels and remediation levels using information on total PCB concentrations and the cancer slope factor for PCB mixtures published in the Integrated Risk Information System (IRIS) database.

Ecology's Rulemaking Proposal and Rationale

In the draft rule revisions distributed in June 2006, Ecology proposed to revise WAC 173-340-708(8) to provide the option for cleanup for Ecology and others to use the WHO-1998 TEF values and methodology when calculating excess cancer risk, cleanup levels and remediation levels for PCB mixtures (Option 2). Ecology is also considering specifying the use of the WHO-2005 values that were published on-line in early July. Ecology's rationale for selecting this option includes the following:

- Effective Tool for Assessing Environmental Risks: The TEF methodology is a tool that allows the assessor to evaluate the toxicity of a complex environmental mixture in the absence of complete knowledge of the toxicity for all of the components of the mixture. EPA has used the TEF methodology to evaluate the risks of PCB contamination in and around the Hudson River, the

[47] Van den Berg M, Birnbaum L, Bosveld, ATC, Brunstrom B, Cook P, Feeley M, Giesy JP, Hanberg A, Hasegawa R, Kennedy SW, et al. (1998). Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environmental Health Perspectives 106(12):775-792. This peer-reviewed publication is the technical standard for using WHO-recommended TEFs for polychlorinated dibenzo-*p*-dioxins and dibenzofurans and dioxin-like PCBs.

[48] The scientific experts expressed continued support for the TEF approach. However, they identified changes to the TEF values for four of the seventeen dioxin and furan congeners: 2,3,4,7,8-pentachlorodibenzofuran (TEF revised from 0.5 to 0.3); 1,2,3,7,8-pentachlorodibenzofuran (TEF revised from 0.05 to 0.03); and octachlorodibenzo-p-dioxin and octachlorodibenzofuran (TEF revised from 0.0001 to 0.00003)

Housatonic River, and in the EPA's Great Lakes Initiative. NRC (2001) concluded that congener-specific analyses often provide a better basis for assessing environmental risks because:

- After release into the environment, PCB mixtures change through partitioning, transformation, and bioaccumulation, differing considerably from commercial mixtures.
- There is a selective retention of persistent PCB congeners through the food chain (enrichment) that confers greater exposure and potential risks.
- Persistent congeners can retain biological activity long after exposure stops.
- Half-life estimates for a PCB mixture can underestimate its long – term persistence, because half-lives of its components differ widely.
- Environmental PCBs occur as mixtures, there are no cancer studies of PCB mixtures found in the environment. Studies are available for some commercial Aroclor mixtures, though similarity to an environmental mixture can be uncertain. This uncertainty results because mixtures are partitioned, transformed, and bioaccumulated in the environment. Testing an Aroclor mixture in the laboratory may not be a valid surrogate for assessing a Aroclor mixture that has been in the environment.

- Biological Basis: The TEF approach for dioxin-like PCBs is based on the concept that the various congeners of dioxin-like PCBs essentially act as one chemical, affecting the Ah receptor (aryl hydrocarbon hydroxylase receptor, enzyme induction).
- Scientific Review: The WHO-98 TEF values are based on a rigorous scientific review and professional consensus. More recent scientific reviews conducted by the EPA Risk Assessment Forum (EPA, 2000), EPA's Science Advisory Board (EPA, 1995; EPA, 2001), the World Health Organization (Van den Berg et. al., 1998) and the National Research Council (NAS, 2003; NRC, 2001) have re-affirmed the scientific basis for these values.
- Current Investigations and Evaluations at Cleanup Sites in Washington. Congener-specific analyses are being performed as part of several ongoing remedial investigations in Washington State.
- Other Environmental Programs: Ecology has reviewed the methods and procedures used by other environmental programs to characterize PCB mixtures. Several agencies currently use the WHO-98 TEF values and methodology to evaluate health risks and establish regulatory requirements for PCB mixtures. For example:
  - When preparing the 303(d) list of impaired water bodies, the Environmental Assessment Program calculated TEQs for dioxins/furans and PCBs in fish tissue and surface water in freshwater environments using the WHO-98 TEF values. The Water Quality Program used this evaluation to identify impaired waterbodies by comparing the total TEQs for dioxins/furans and PCBs relative to the NTR criterion for 2, 3, 7, 8-TCDD and total PCBs (64 FRN 61195) with a designated 10^{-6} risk level (Ecology, 2004).
  - EPA's Superfund Program uses the methods and procedures described in IRIS for evaluating mixtures of PCBs[49]. The EPA Superfund program also recommends that the risk of dioxin-like congeners be considered (using WHO-98 values) when evaluating the health risks posed by PCB mixtures (EPA 2000 and 2003b; EPA, 2003).
  - Several environmental agencies in other states currently use the WHO-98 TEF values for dioxin-like PCBs when evaluating excess cancer risks and establishing regulatory requirements. States using the WHO-98 TEF values for dioxin-like PCBs include California[50], Louisiana[51], Massachusetts[52], Minnesota[53], Oregon[54] and Texas[55].

[49] EPA includes the following statement in the IRIS database entry for PCBs: When congener concentrations are available, the slope-factor approach can be supplemented by analysis of dioxin TEQs to evaluate dioxin-like toxicity. Risks from dioxin-like congeners (evaluated using dioxin TEQs) would be added to risks from the rest of the mixture (evaluated using slope factors applied to total PCBs reduced by the amount of dioxin-like congeners).
[50] California EPA, 2005

- Practical Considerations: Congener-specific analyses are more expensive than total PCB analyses and, consequently, may not be appropriate for smaller cleanup sites.
- Completeness of Assessment: PCB toxicity includes both dioxin-like and non-dioxin-like modes of action that contribute to the overall toxicity of PCB mixtures. Dioxin equivalence evaluates the toxicity of only the dioxin-like PCB portion of the PCB mixtures. Non-dioxin-like toxicity, in turn, includes both cancer and non-cancer effects due to different modes of action. Although evaluation methods of PCB effects continue to evolve, dioxin-like toxicity (as evaluated with TEF methodology) is an important component of PCB toxicity that should be considered when evaluating these mixtures. Failure to include dioxin-like PCB toxic equivalents in the evaluation of the toxicity and assessment of the risks of complex environmental mixtures containing dioxins, furans, and dioxin-like PCBs could potentially underestimate the risks posed by these mixtures. The Centers for Disease Control (2000), in estimating the body burden of dioxin like chemicals in human adipose tissue, estimated that 17% of the TEQ were from dioxin-like PCBs and 82% of the TEQs came from dioxins and furans. The relative percentage of dioxin-like PCB TEQs to dioxin and furan TEQs is much higher in Alaskan natives. Two recent studies from Washington State have measured dioxin-like chemicals in wood ash and agricultural soils. These studies addressed the contribution of dioxin-like PCBs to total TEQ (Delistraty and Singleton, 2001; and, Delistraty and Laflamme, 2001). In this study it was noted that although the contribution of dioxin-like PCBs to total TEQ in wood ash was relatively minor (<1%), a national survey of dioxins in biosolids indicated that dioxin-like PCBs comprised approximately 21% of total TEQ in biosolids (Alvarado et al, 2001).

Table 6: Toxicity Equivalency Factors (TEFs) For Polychlorinated Biphenyls (PCBs)

IUPAC #	Structure	WHO/94[56]	WHO/98[57]	WHO/05
77	3,3',4,4'-TCB	0.0005	0.0001	0.0001
81	3,4,4',5-TCB	-------	0.0001	0.0003
105	2,3,3',4,4'-PeCB	0.0001	0.0001	0.00003
114	2,3,4,4',5-PeCB	0.0005	0.0005	0.00003
118	2,3,4,4',5-PeCB	0.0001	0.0001	0.00003
123	2,3,4,4',5-PeCB	0.0001	0.0001	0.00003
126	3,3',4,4',5- PeCB	0.1	0.1	0.1
156	2,3,3',4,4',5-HxCB	0.0005	0.0005	0.00003
157	2,3,3',4,4',5-HxCB	0.0005	0.0005	0.00003
167	2,3,4,4',5,5'- HxCB	0.00001	0.00001	0.00003
169	3,3',4,4',5,5'- HxCB	0.01	0.01	0.03
170	2,2',3,3',4,4',5-HpCB	0.0001	-------	-------
180	2,2',3,4,4',5,5'-HpCB	0.00001	-------	-------
189	2,3,3',4,4',5,5'-HpCB	0.0001	0.0001	0.00003

[51] ATSDR Health Consultation, Review of 2002 Eunice City Lake Fish Investigation Eunice, Louisiana. July 27, 2005
[52] Housatonic Superfund Site Risk Assessment
[53] Minnesota Department of Health. Risk Assessment Rules/Guidance. Polycyclic Aromatic Hydrocarbons:Methods for Estimating Health Risks from Carcinogenic PAHs.
[54] Oregon Department of Environmental Quality. E-Mail From M. Poulsen (OR DEQ) to Dr. M. Bailey (EPA, R. 10) March 30, 2006.
[55] Texas Administrative Code, Title 30, Part 1, Chapter 350 subchapter D, Rule 350.76, (e)(1)(A)
[56] Ahlborg, U; Becking, GC; Birnbaum, LS; et al. (1994) Toxic equivalency factors for dioxin-like PCBs: report on a WHO-ECEH and IPCS consultation, Dec. 1993. Chemosphere 28(6):1049-1067.
[57] Van den Berg, M; Birnbaum, L; Bosveld, ATC; et al. (1998) Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environ Health Perspect 106(12):775-792.

Cleanup Levels for PCB Mixtures

Issue # 7

Should PCB mixtures be treated as a single hazardous substance or a mixture of multiple hazardous substances when calculating excess cancer risks and determining compliance with cleanup and remediation levels under MTCA?

Background

Under the current MTCA rule, cleanup levels for PCB mixtures are established using the appropriate cancer slope factor for PCB's published in the Integrated Risk Information System (IRIS) database. Compliance with PCB cleanup levels is evaluated using measurements of total PCBs in soil or other environmental media (the sum of all Aroclors). Under this approach, PCB mixtures are treated as a single hazardous substance when establishing cleanup levels.

Application of the TEF approach to PCB congeners raises questions in terms of how this information will be used when establishing cleanup levels. These questions are similar to those identified for dioxin and furan mixtures (See Issue #2). Specifically, Ecology will need to decide whether to either (1) continue to treat PCB mixtures as a single hazardous substance (using a total toxic equivalence concentration to characterize the mixture) or (2) treat each congener as an individual hazardous substance.

MTCA Rulemaking Options

Ecology has considered three options for resolving this issue:

1. Each Dioxin-Like PCB Congener Treated as a Single Hazardous Substance: Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one-in-one million (10^{-6}). Cleanup levels for other dioxin-like PCB congeners would be established by dividing the TCDD cleanup level by the applicable congener-specific TEF. Because there is an overall limit on cancer risk under MTCA of one-in-one hundred thousand (1×10^{-5}), when more than 10 dioxin-like PCB congeners and other carcinogens are present at a site, the cleanup levels for individual congeners would need to be adjusted downward to insure this overall risk limitation is not exceeded. If there are multiple pathways of exposure, a further downward adjustment of individual congeners would also need to be made.
2. PCB Mixture Treated as a Single Hazardous Substance: Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one in one million (10^{-6}). The TEF methodology would be used to calculate a TEQ (based on the 12 dioxin-like PCB congeners identified in Table 6) for environmental samples that would then be compared to the TCDD cleanup level.
3. Mixtures of All Dioxin-like Compounds Treated as a Single Hazardous Substance: Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one in one million (10^{-6}). The TEF methodology would be used to calculate a TEQ (based on the 17 dioxin/furan congeners identified in Table 1 and the 12 PCB congeners identified in Table 6) for environmental samples that would then be compared to the TCDD cleanup level.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to clarify that PCB mixtures will continue to be considered a single hazardous substance for assessing carcinogenic risk under MTCA (Option 2). Ecology's rationale for selecting this option includes the following:

- Biological Basis: The TEF approach for dioxin-like PCBs is based on the concept that the various congeners of dioxin-like PCBs essentially act as one chemical, affecting the Ah receptor (aryl hydrocarbon hydroxylase receptor, enzyme induction). The Agency for Toxic Substances and Disease Registry (ATSDR) recognizes the TEF methodology in its respective toxicological profiles for mixtures of chlorinated dibenzo-p-dioxins and polychlorinated biphenyls (ATSDR, 1998 and 2000).

- Current Practice Under MTCA: Option 2 is consistent with the approach used for PCB mixtures in the current MTCA rule. PCB mixtures have been historically treated as a single hazardous substance when developing Method B and C cleanup levels or determining compliance with the Method A cleanup levels. In addition, MTCA cleanup levels must be at least as stringent as legally applicable and relevant and appropriate requirements (ARARs) established under other state and federal environmental laws. As discussed below, Option 2 is consistent with approaches used by other Ecology programs and/or EPA to establish requirements that are considered ARARs under MTCA.

- Other Ecology Programs: Several other Ecology programs use approaches similar to Options 2 and/or 3 when establishing requirements for PCB mixtures or evaluating compliance with those requirements. For example:

  - The Air Quality Program specifies risk-based acceptable source impact levels for Class A toxic air pollutants using unit risk factors published in EPA's Integrated Risk Information System (IRIS). When performing these evaluations, PCB mixtures are treated as a single hazardous substance in the same way as other toxic air pollutants such as arsenic or trichloroethylene.

  - The Water Quality Program uses surface water human health criterion for marine and freshwaters identified in the National Toxics Rule for PCBs as a single numeric criterion for all PCBs. The EPA's National Recommended Water Quality Criteria for 2002 reaffirms the consideration of PCBs as a single hazardous substance stating: The polychlorinated biphenyl (PCB) numeric criterion for the protection of human health applies to total PCBs which is the sum of all homolog, all isomer, all congener, or all Aroclor analyses. Consequently, this option is consistent with the minimum cleanup standard for surface waters in Washington.

  - The Environmental Assessment Program (EAP) evaluates and identifies impaired water bodies due to PCB contamination using TEF methodology which considers PCB mixtures as a single hazardous substance (Ecology, 2004) For example, the Water Quality Program used the WHO-98 methodology when establishing the Total Maximum Daily Load for Lake Chelan based on an evaluation conducted by EAP. In that evaluation, Ecology used congener-specific data and the TEF values to calculate TEQs which were used to characterize environmental concentrations. The TEQ values were compared with the National Toxics Rule criterion for TCDD which is based on a 10^{-6} risk level (Ecology, 2005). When preparing the 303(d) list of impaired water bodies, the Environmental Assessment Program calculated TEQs for dioxins/furans and PCBs in fish tissue and surface water in freshwater environments using the WHO-98 TEF values. Ecology identified impaired waterbodies by comparing the total TEQs for dioxins/furans and PCBs relative to the NTR criterion for TCDD and total PCBs (64 FRN 61195) with a designated 10^{-6} risk level (Ecology, 2004).

- Consistency With Ecology's Initiatives on Toxic Chemicals: Public concerns about health threats posed toxic chemicals have grown over the last decade as new information on toxicity and body burdens have become available. Ecology has undertaken several initiatives to reduce and cleanup sources of bioaccumulative chemicals in Puget Sound and other parts of the state. Selection of an option that relaxes cleanup requirements for chemical mixtures (Option 1) would be inconsistent with these Ecology initiatives.

- Other State and Federal Environmental Programs: Ecology has reviewed the methods and procedures used by other environmental programs to characterize PCB mixtures. These programs differ in terms of analytical parameters (e.g. total PCB analysis vs dioxin-like PCB congener analysis), regulatory focus (e.g. site cleanup, water quality, etc.) and risk policies. However, the vast majority of programs reviewed by Ecology treat PCB mixtures as a single hazardous substance when establishing regulatory requirements. For example:
  - EPA has established a maximum contaminant level for PCBs under the Safe Drinking Water Act. The MCL establishes a single numeric standard (0.0005 mg/L) for total PCBs. The Washington Board of Health has adopted an identical drinking water standard for PCBs (WAC 246-290-310).
  - The EPA Superfund Program uses the methods and procedures described in IRIS for evaluating mixtures of PCBs. PCB mixtures are treated as a single hazardous substance.
  - The Agency for Toxic Substances and Disease Registry (ATSDR) uses the TEF methodology to evaluate the toxicity and assess the risks of PCB mixtures. For example, ATSDR evaluated the health risks associated with eating PCB contaminated fish in Eunice City Lake, Eunice City, Louisiana. In this evaluation, ATSDR calculated TEQs using the WHO-98 TEFs for the 12 dioxin-like PCB congeners. The TEQs for each fish species were compared to the EPA Region III risk-based concentration for the carcinogenic effects of TCDD in fish tissue. The protective risk based concentration for TCDD in fish tissue was associated with an excess cancer risk of one in one million (10^{-6}).
  - The FDA uses the TEF methodology and toxicity equivalents to monitor food and animal feed with the goal of reducing dietary exposure to dioxin-like compounds (FDA, 2005).
  - Ecology reviewed the methods and procedures used by several other state environmental programs. Most states have established cleanup levels for total PCBs that treat the mixture as a single hazardous substance. Several states also use the WHO-98 TEF values and methodology to evaluate dioxin-like PCBs. Many of these states treat mixtures of dioxin-like PCBs as if the mixture (characterized by the TEQ) was a single hazardous substance. Some states (e.g. Texas) calculate TEQs that reflect the sum of dioxins, furans and dioxin-like PCBs.
- Consideration of Multiple Substances and Multiple Pathways: The MTCA Cleanup Regulation specifies that Method B and C cleanup levels established for individual hazardous substances based on a particular pathway (e.g. soil ingestion) must be adjusted downward to take into account exposure to multiple hazardous substances and/or multiple exposure pathways in situation where total excess cancer risk would exceed 10^{-5}. Treating PCB mixtures as a single hazardous substance minimizes the need for such adjustments and simplifies the process for establishing cleanup levels.

Consideration of Non-Dioxin Health Effects Associated With PCB Mixtures

Issue # 8

How should Ecology take into account non-dioxin-like health effects when using the TEF methodology to assess the potential carcinogenic risk of PCB mixtures under MTCA?

Background

Under the MTCA Cleanup Regulation, excess cancer risks, cleanup levels and remediation for PCB mixtures are currently established using information on the total PCB concentrations at a site and the cancer slope factor for PCBs published in the Integrated Risk Information System (IRIS) database.

However, there is a sizable body of scientific information supporting the use of a TEF methodology to characterize PCB mixtures. EPA (1991)[58] concluded that selected PCBs may share a common mode of action with 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). Ahlborg et al. (1994)[59] toxicity equivalency factors (TEFs) are considered to be applicable to PCBs for the health endpoint of cancer through the common mode of action shared with TCDD.

In 1998 the World Health Organization (WHO)-European Center for Environmental Health and the International Program on Chemical Safety generated a database consisting of approximately 1,200 peer-reviewed publications evaluating the toxicity of PCBs. The WHO proposed TEF values for 12 dioxin-like PCBs based on their evaluation of this database. The proposed WHO-98 TEF values for polychlorinated biphenyls were published by Van den Berg et al. (1998)[60] and have been recognized by national and international regulatory agencies (Cal EPA, 2005).

MTCA Rulemaking Options

Ecology has considered three options for resolving this rulemaking issue:

1. Limit evaluation of PCB congeners to those with dioxin-like effects: Under this option, the 12 dioxin-like congeners identified by the World Health Organization would be used to characterize the health risks for the whole mixture;

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[58] U.S. EPA. 1991. Workshop report on toxicity equivalency factors for polychlorinated biphenyl congeners. Risk Assessment Forum. EPA/625/3-91/020. The purpose of the 1991 EPA workshop was to examine the existing toxicity and exposure database on PCBs to ascertain the feasibility of developing toxicity equivalency factors for dioxin-like PCB congeners.

[59] Ahlborg UG, Becking GC, Birnbaum LS, Brouwer A, Derks HJGM, Feeley M, Golor G, Hanberg A, Larsen JC, Liem AKD, et al. 1994. Toxic equivalency factors for dioxin-like PCBs; report on a WHO-ECEH and IPCS consultation. Chemosphere 28 (6): 1049-1067. The results of the 1991 EPA workshop were published in this peer-reviewed technical publication.

[60] Van den Berg M, Birnbaum L, Bosveld, ATC, Brunstrom B, Cook P, Feeley M, Giesy JP, Hanberg A, Hasegawa R, Kennedy SW, et al. (1998). Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environmental Health Perspectives 106(12):775-792. This peer-reviewed publication is the technical standard for using WHO-recommended TEFs for polychlorinated dibenzo-*p*-dioxins and dibenzofurans and dioxin-like PCBs.

2. Separately evaluate dioxin-like health effects and non-dioxin health effects: Under this option, Method B cleanup levels would be based on the endpoint resulting in the most stringent cleanup level.

3. Perform an integrated evaluation of dioxin-like health effects and non-dioxin-like health effects: Under this option, Method B cleanup levels would be established at concentrations where the cancer risk from all congeners does not exceed an incremental cancer risk of one-in-one million (10^{-6}).

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to specify that an integrated evaluation of dioxin-like and non-dioxin-like health effects should be evaluated when using toxicity equivalency factors and methodology described in Van den Berg et. al. (1998) to evaluate the potential carcinogenic risk of mixtures of dioxin-like PCBs. Ecology's rationale for selecting this option includes the following:

- Biological Basis: PCB toxicity includes both dioxin-like and non-dioxin-like modes of action that contribute to the overall toxicity of PCB mixtures. Dioxin equivalence evaluates the toxicity of only the dioxin-like PCB portion of the PCB mixtures. Non-dioxin-like toxicity includes both cancer and non-cancer effects due to different modes of action. Although evaluation methods of PCB effects continue to evolve, dioxin-like toxicity (as evaluated with TEF methodology) is an important component of PCB toxicity that requires consideration.

- Scientific Consensus: The WHO-98 TEF values are based on a rigorous scientific review and professional consensus. More recent scientific reviews conducted by the EPA Risk Assessment Forum (EPA, 2000), EPA Science Advisory Board (EPA, 1995; and 2003), the World Health Organization (Van den Berg et. al., 1998) and the National Research Council (NAS 2003; NRC 2001; NAS 2006) have re-affirmed the scientific basis for these values.

- EPA Guidance. An integrated evaluation of dioxin-like and non-dioxin-like health effects for PCBs would follow the general guidance provided by EPA's Integrated Risk Information System:

> When congener concentrations are available, the slope-factor approach can be supplemented by analysis of dioxin TEQs to evaluate dioxin-like toxicity. Risks from dioxin-like congeners (evaluated using dioxin TEQs) would be added to risks from the rest of the mixture (evaluated using slope factors applied to total PCBs reduced by the amount of dioxin-like congeners).

Use of TEF Values When Evaluating Cross-Media Transfer

Issue # 9

How should Ecology apply the TEF methodology when evaluating cross-media impacts?

Background

Mixtures of polychlorinated dibenzo-p-dioxins and dibenzofurans, polychlorinated biphenyls, and polycyclic aromatic hydrocarbons exist in the environment as complex chemical mixtures. The Department of Ecology has determined these mixtures are persistent, bioaccumulative toxins (WAC 173-333-100). This means these complex environmental mixtures remain in the environment for long periods of time with the potential to transfer from one medium to another and accumulate in the food chain.

Models are typically used to predict how these chemical mixtures migrate from one medium to another (e.g. leaching from soil to groundwater) and bioaccumulate (concentrate in fish from water or sediment). The transport and partitioning of these complex environmental mixtures are determined, in part, by physicochemical properties such as water solubility, vapor pressure, Henry's law constant, and octanol-water partition coefficient. This "cross media" transport of these mixtures is complicated by the fact that these mixtures are made up of congeners or different PAHs each with different physicochemical properties and that the composition of the mixtures changes over time (weathering) through partitioning, chemical transformation, and preferential bioaccumulation. Environmental partitioning of a chemical refers to the processes by which mixtures, or components of the mixture, separate into air, water, sediment, and soil

MTCA Rulemaking Options

Ecology has considered two options for resolving this rulemaking issue:

1. Index Chemical: Under this option, cleanup proponents would use the chemical properties of the index chemical (e.g. TCDD, BaP) when modeling the fate and transport of dioxin/furan, PAH and PCB mixtures.
2. Congener-Specific Analysis: Under this option, cleanup proponents would use congener-specific properties, when available, when modeling the fate and transport of dioxin/furan, PAH and PCB mixtures.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to require that congener-specific properties by used when modeling the fate and transport of mixtures of dioxin/furans, PCBs and PAHs. Ecology's rationale for selecting this option includes the following:

- Technical Basis: The fate and transport of dioxins, furans, PCBs and PAHs are not necessarily not related to their TEFs. A wide range of other physical and chemical characteristics influence the persistence, mobility and transport of contaminants in the environment.

- Scientific Review: NAS (2003) has reviewed the application of the TEF methodology to dioxin/furan mixtures and concluded "…[a]lthough the TEF system is useful for determining toxicity in mixtures of DLC congeners, it cannot be used to simplify environmental fate and transport analyses of DLCs because individual congeners differ in their physical and chemical properties, an important consideration in fate modeling…" (p. 20). NRC (2001) reached similar conclusions in its review of PCB contamination.

- Approaches Used By Other Agencies: EPA Region V has developed a Total Equivalency Approach that is designed to allow variations in bioaccumulation potential to be considered when establishing water quality criteria for dioxin/furan mixtures. This approach involves multiplying each TEF value for each congener by a corresponding bioconcentration equivalency factor (BEFs) to calculate a Total Equivalency for the mixture. This approach is being used by the water quality programs in New York and several other Great Lakes states. The Oregon DEQ is considering adopting a similar approach.

- Practical Considerations: Congener-specific information is available for the physical and chemical characteristics that influence the environmental fate and transport of dioxin, furans, PCBs and PAHs. Site-specific evaluations of fate and transport can be streamlined through the use of spreadsheet models. For example, Ecology has developed a spreadsheet model to estimate the fate and transport of petroleum contaminants (including PAHs) that have been released into soils.

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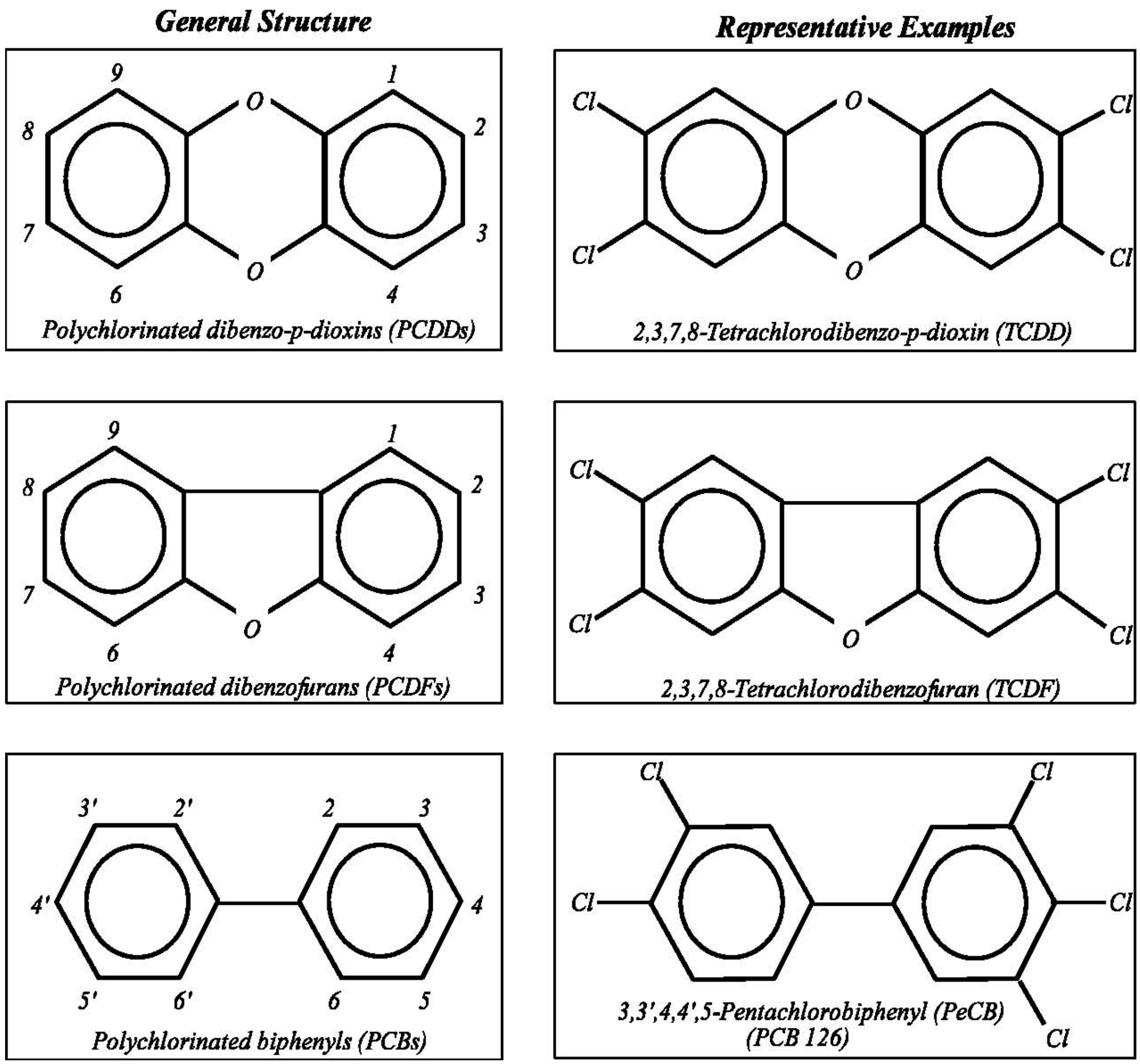
6 Representative Structural Formulas

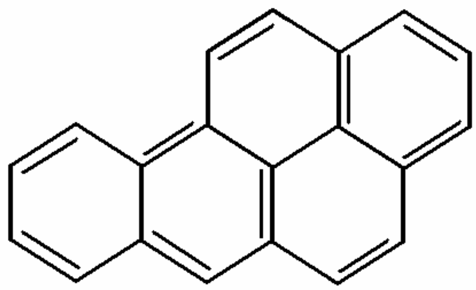
Polychlorinated dibenzo-p-dioxins and dibenzofurans
Polychlorinated biphenyls



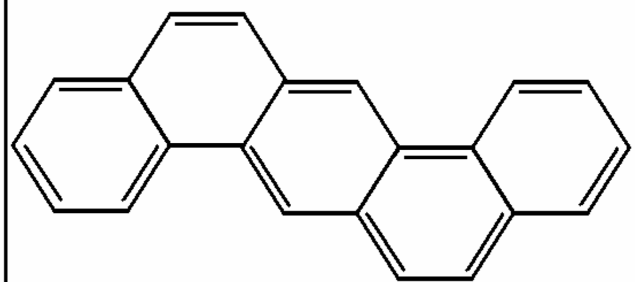
Chemical structures of polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and polychlorinated biphenyls. Numbers by aromatic ring carbons of general structures represent potential chlorine substitutions.

Polycyclic Aromatic Hydrocarbons

Representative Examples



Benzo[a]pyrene



Dibenzo[a,h]anthracene